

WO2006112849

Publication Title:

SINGLE FOLD DEVICE FOR TISSUE FIXATION

Abstract:

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Courtesy of <http://worldwide.espacenet.com>

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau



(43) International Publication Date
26 October 2006 (26.10.2006)

PCT

(10) International Publication Number
WO 2006/112849 A1

(51) International Patent Classification:
A61B 17/072 (2006.01) A61B 17/068 (2006.01)

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(21) International Application Number:
PCT/US2005/013740

(81) Designated States (unless otherwise indicated, for every kind of national protection available): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SM, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

(22) International Filing Date: 21 April 2005 (21.04.2005)

(84) Designated States (unless otherwise indicated, for every kind of regional protection available): ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IS, IT, LT, LU, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

(25) Filing Language: English

Published:

— with international search report

[Continued on next page]

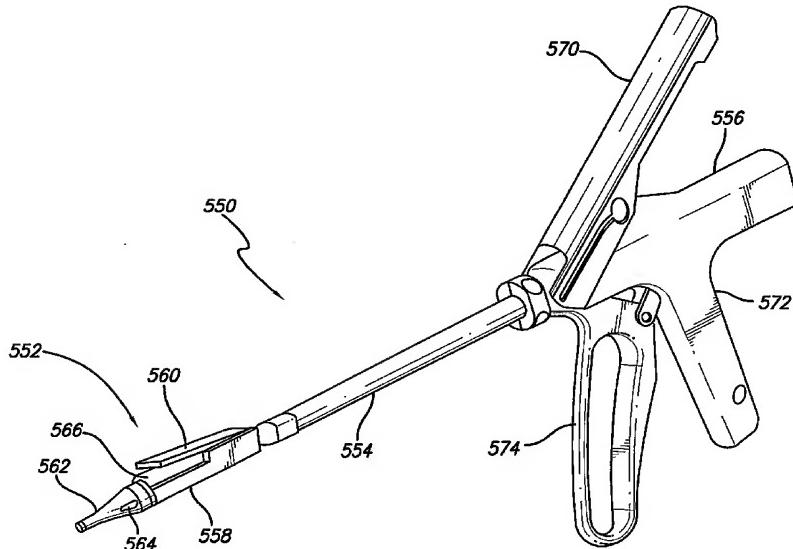
(26) Publication Language: English

(30) Priority Data:
Not furnished 15 April 2005 (15.04.2005) US

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(54) Title: SINGLE FOLD DEVICE FOR TISSUE FIXATION



WO 2006/112849 A1

(57) Abstract: A system for tissue approximation and fixation is described herein. A device is advanced in a minimally invasive manner within a patient's body to create one or several divisions or plications within a hollow body organ. The system comprises a stapler assembly having a tissue acquisition member and a tissue fixation member. The stapler assembly approximates tissue from within the hollow body organ with the acquisition member and then affixes the approximated tissue with the fixation member. In one method, the system can be used as a secondary procedure to reduce the size of a stoma within the hollow body organ.



For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

SINGLE FOLD DEVICE FOR TISSUE FIXATION

Cross-Reference To Related Application

This application is a continuation-in-part of co-pending application Serial 5 No. 10/686,326 filed on October 14, 2003, which is herein incorporated by reference.

Background of the Invention

1. Field of the Invention:

The present invention relates generally to medical apparatus and methods. More 10 particularly, it relates to devices and methods for approximating portions of a hollow body organ, particularly a stomach, intestine, or other region of the gastrointestinal tract, while affixing the tissue.

2. General Background and State of the Art:

In cases of severe obesity, patients may currently undergo several types of surgery 15 either to tie off or staple portions of the large or small intestine or stomach, and/or to bypass portions of the same to reduce the amount of food desired by the patient, and the amount absorbed by the gastrointestinal tract. The procedures currently available include laparoscopic banding, where a device is used to "tie off" or constrict a portion of the stomach, vertical banded gastroplasty (VBG), or a more invasive surgical procedure 20 known as a Roux-En-Y gastric bypass to effect permanent surgical reduction of the stomach's volume and subsequent bypass of the intestine.

Typically, these stomach reduction procedures are performed surgically through an open incision and staples or sutures are applied externally to the stomach or hollow body organ. Such procedures can also be performed laparoscopically, through the use of smaller 25 incisions, or ports, through trocars and other specialized devices. In the case of laparoscopic banding, an adjustable band is placed around the proximal section of the stomach reaching from the lesser curve of the stomach around to the greater curve, thereby creating a constriction or "waist" in a vertical manner between the esophagus and the pylorus. During a VBG, a small pouch (approximately 20 cc in volume) is constructed by 30 forming a vertical partition from the gastroesophageal junction to midway down the lesser curvature of the stomach by externally applying staples, and optionally dividing or resecting a portion of the stomach, followed by creation of a stoma at the outlet of the partition to prevent dilation of the outlet channel and restrict intake. In a Roux-En-Y gastric bypass, the stomach is surgically divided into a smaller upper pouch connected to

the esophageal inflow, and a lower portion, detached from the upper pouch but still connected to the intestinal tract for purposes of secreting digestive juices. A resected portion of the small intestine is then anastomosed using an end-to-side anastomosis to the upper pouch, thereby bypassing the majority of the intestine and reducing absorption of
5 caloric intake and causing rapid "dumping" of highly caloric or "junk foods".

Although the outcome of these stomach reduction surgeries leads to patient weight loss because patients are physically forced to eat less due to the reduced size of their stomach, several limitations exist due to the invasiveness of the procedures, including time, use of general anesthesia, time and pain associated with the healing of the incisions,
10 and other complications attendant to major surgery. In addition, these procedures are only available to a small segment of the obese population (morbid obesity, Body Mass Index \geq 40) due to their complications, leaving patients who are considered obese or moderately obese with few, if any, interventional options.

In addition to surgical procedures, certain tools exist for approximating or
15 otherwise securing tissue such as the stapling devices used in the above-described surgical procedures and others such as in the treatment of gastroesophageal reflux disease (GERD). These devices include the GIA® device (Gastrointestinal Anastomosis device manufactured by Ethicon Endosurgery, Inc. and a similar product by USSC), and certain clamping and stapling devices as described in United States Patent Nos. 5,403,326;
20 5,571,116; 5,676,674; 5,897,562; 6,494,888; and 6,506,196 for methods and devices for fundoplication of the stomach to the esophagus for the treatment of gastroesophageal reflux disease (GERD). In addition, certain tools, such as those described in United States Patent Nos. 5,788,715 and 5,947,983, detail an endoscopic suturing device that is inserted through an endoscope and placed at the site where the esophagus and the stomach meet.
25 Vacuum is then applied to acquire the adjacent tissue, and a series of stitches are placed to create a pleat in the sphincter to reduce the backflow of acid from the stomach up through the esophagus. These devices can also be used transorally for the endoscopic treatment of esophageal varices (dilated blood vessels within the wall of the esophagus).

There is a need for improved devices and procedures. In addition, because of the
30 invasiveness of most of the surgeries used to treat obesity and other gastric disorders such as GERD, and the limited success of others, there remains a need for improved devices and methods for more effective, less invasive hollow organ restriction procedures.

Summary Of The Invention

A system for tissue approximation and fixation is described which may be used to approximate tissue regions from within a hollow body organ, such as the stomach, esophageal junction, and other portions of the gastrointestinal tract. Generally, the devices 5 of the system may be advanced in a minimally invasive manner within a patient's body, *e.g.*, transorally, endoscopically, percutaneously, *etc.*, to create one or several divisions or plications within the hollow body organ. Examples of placing and/or creating divisions or plications may be seen in further detail in U.S. Pat. No. 6,558,400; U.S. Pat. App. Serial No. 10/188,547 filed July 2, 2002; and U.S. Pat. App. Serial No. 10/417,790 filed April 16, 10 2003, each of which is incorporated herein by reference in its entirety. The system may comprise at least a tissue acquisition and folding device and a tissue stapling or fixation device, each of which may be used together as a single system.

The folder assembly may generally comprise, in part, a pod assembly which may be used to initially acquire and approximate the tissue to be folded. The pod assembly 15 may comprise a first pod member and a second pod member, each of which may be independently articulatable to form a first compact configuration and a second larger, expanded configuration. Each of the pod members may be connected to respective first and second actuation rods on the distal end of a yoke member, which connects the pod members to an elongate working body or shaft. The working body itself may be 20 comprised of a plurality of aligned link members which are adapted to provide some flexibility to the working body and which defines a main lumen throughout a length of the working body as well as through the handle connected to a proximal end of the working body. Moreover, the working body may be covered by a sheath or a covering to enhance the lubricity of the shaft as well as to maintain the interior of the working body clear from 25 body fluids and debris and seal the shaft to allow insufflation of the target organ. Various materials may be utilized for the sheath including various plastics, elastomers, latex, polyurethane, thermoplastics, *e.g.*, PTFE, silicone, PVC, FEP, Tecoflex®, Pebax®, *etc.*, so long as they are preferably biocompatible.

One or both of the pod members may additionally define a vacuum chamber or 30 opening into which the tissue may be drawn within. The opening of the vacuum chamber may be slotted along a direction parallel to a longitudinal axis of the working body; alternatively, the opening may be defined a variety of shapes, *e.g.*, oval, elliptical, *etc.*, and furthermore may be offset such that it is defined transverse to the longitudinal axis of the working body. Adjacent to and preferably parallel with the vacuum chamber is a

tensioning arm or member, which may have a length equal to that of the vacuum chamber. Alternatively, a length of the tensioning member may be less than or greater than that of vacuum chamber. The distal end of each pod member may have a flexible and/or atraumatic tip such as a blunt, rounded, or "bullet" tip, made from any number of polymers 5 to facilitate the guidance of the pod assembly into the hollow body organ without damaging tissue along the way.

A guidewire may optionally be used with the folder assembly during initial deployment and positioning within the hollow body organ in a manner similar to a catheter for guiding the pod assembly to a predetermined position. The use of the guidewire may 10 assist in initial placement of the device transorally, and it can also be exchanged through a lumen in the tip of one or both of the pod tips. Both of the first and second pod members may each be adapted to pivot on respective hinge members such that in a first compact configuration, the first and second pod members are immediately adjacent to one another. When desirably positioned within the hollow body organ, a vacuum force may be applied 15 within one or both of the pod members such that tissue begins to enter within one or both of the vacuum chambers or openings. To assist in placement of the device, various indicators may be used. For instance, one or several indicators may be located directly on the device or indicators may be utilized with the device in relation to anatomical structures or landmarks. In one example, an orientation marker may be placed at a point on the distal 20 portion of the device that is visible endoscopically and can be adjusted relative to structures such as the "z-line" of the gastroesophageal, *i.e.*, the place where a change in color of the tissue from whitish (esophagus) to a salmon color (stomach) occurs delineating what is referred to as the squamocolumnar junction, *i.e.*, the point where the lining changes from esophageal (squamous) to stomach (columnar). Then, in moving to a 25 second expanded configuration, one or both of the first pod member and/or the second pod member may be translated via actuation rods into opposing radial directions from one another such that the opposing areas of tissue are approximated to create an overlap region. Once this overlap region has been desirably created, the fixation assembly may be advanced distally through the main lumen of the folder assembly and positioned upon 30 exiting the main lumen to become clamped directly over the overlapped tissue. It is also within the scope of this disclosure to actuate the pods simultaneously, serially or singularly where only one fold of tissue is manipulated and fastened.

Vacuum tubes may be routed through the length, or a partial length, of the working body for communication with the pod assembly. The proximal ends of the vacuum tubes

may be connected to one or more vacuum pumps. Furthermore, the vacuum tubes may utilize braided materials, *e.g.*, stainless steel or superelastic materials such as Nickel-Titanium alloy, integrated throughout to prevent kinking or pinching of the tubes.

The fixation assembly comprises, in part, a manipulatable stapler assembly
5 connected via a flexible shaft to a stapler handle. The stapler assembly itself generally comprises a staple cartridge housing within which one or more staples are housed. A corresponding anvil is positioned in apposition to the staple cartridge housing and may be used to provide a staple closure surface when tissue to be affixed is adequately positioned between the staple cartridge housing and the anvil. With the stapler assembly connected at
10 the distal end of a flexible shaft, a handle is connected at the proximal end of the shaft. The handle itself may allow the surgeon or user to hold and manipulate the fixation assembly while articulating the stapler assembly between an open and closed configuration. Moreover, the configuration of the handle allows the surgeon or user to actuate the stapler assembly as well as deploy the staples from the staple cartridge housing.

In use, the fixation assembly may be advanced within the folder assembly main lumen with the fixation assembly configured in a closed configuration. To maintain an orientation, *i.e.*, rotational stability, of the fixation assembly relative to the folder assembly and the approximated tissue, the fixation assembly may be configured to have a shape which is keyed to a cross-sectional area of the folder assembly main lumen. The keyed
15 configuration helps to ensure that as the fixation assembly is advanced through the folder assembly, that the stapler assembly is optimally positioned to be clamped over the tissue for fixation.

When the stapler assembly is advanced and has exited the main lumen of the working body, the staple cartridge housing may be actuated into an open configuration
25 when positioned between distally extending arm members of a yoke to receive the tissue folded between the pod members. The yoke arm members are configured such that when the stapler assembly is positioned therebetween, the stapler assembly is prevented from rotating or bending out of alignment for tissue affixation, *i.e.*, the lateral stability of the stapler assembly is maintained relative to the yoke and the tissue. The stapler assembly
30 may then be advanced distally over the folded tissue and clamped onto the tissue for deploying the staples. To avoid damaging tissue surrounding the pod assembly, one or several insertion indicators may be defined along a portion of flexible shaft of the fixation assembly, preferably near a proximal end of the shaft, to aid the user in knowing when the stapler assembly may be safely articulated while the fixation assembly is positioned within

the working body, *i.e.*, the longitudinal stability of the stapler assembly is maintained relative to the folder assembly. The indicators may be configured to align with a proximal end of the folder handle to correspondingly indicate, *e.g.*, a position of the fixation assembly relative to the folder assembly when the stapler assembly may be opened, and/or
5 how far distally the fixation assembly may be advanced relative to the folder assembly to engage the folded tissue, and when the devices are in a "safe to clamp" mode (*e.g.*, in position around the tissue). Such positional indicators may utilize mechanical features, such as a stop or detent. In addition, the stapler assembly jaws may be spring-loaded open to assist insertion.

10 A tissue fixation device may also include a flexible shaft having a proximal end and a distal end, and a cartridge assembly connected to the distal end of the elongated body. The cartridge assembly includes an acquisition member and a fixation member, wherein the fixation member includes a first jaw and a second jaw capable of pivoting relative to one another from a closed position to an open position. The acquisition member
15 includes a vacuum pod fixed to at least one of the first and second jaws. When the first and second jaws are in the open position, the vacuum pod acquires and holds at least one fold of tissue between the first and second jaws, and the first and second jaws pivot into the closed position to plicate the tissue. The first jaw may be a staple cartridge that houses and ejects a plurality of staples, and the second jaw may be an anvil placed in apposition to
20 the staple cartridge. A handle is disposed at the proximal end of the flexible shaft and includes at least one actuation mechanism adapted to articulate the cartridge assembly from the closed position to the open position, and to deploy a plurality of staples from the cartridge assembly.

Another tissue fixation device is a cross stapler device including a housing or distal frame containing a cartridge assembly and an anvil in apposition to the cartridge assembly.
25 The contacting surfaces of the cartridge assembly and the anvil, which come into contact with one another when the device is actuated, lie in separate planes that are generally perpendicular to the longitudinal axis of the device. A vacuum opening is also disposed on the distal frame between the cartridge assembly and anvil. In use, the vacuum opening is able to acquire and hold at least one fold of tissue between the cartridge assembly and anvil, and cross stapler device is then actuated to fix the fold of tissue together with a plurality of staples. The cross stapler device is configured to form a plicated fold or flap of
30 tissue that is perpendicular to the longitudinal axis of the device.

A method of treating tissue within a hollow body organ may include performing a primary procedure to reduce the volume of the hollow body organ, and then placing at least one plication to increase the success of the primary procedure. The at least one plication may be placed to reinforce the primary procedure, or may be placed to further 5 reduce the volume of the hollow body organ. The at least one plication may also be placed to reduce an orifice created within the hollow body organ, or to close an orifice created within the hollow body organ.

Brief Description of the Drawings

FIG. 1 shows a perspective view of a tissue folding and fixation assembly which 10 may be advanced within a hollow body organ to reconfigure the tissue from within.

FIGS. 2A and 2B show side and top views, respectively, of a pod assembly which may be used to manipulate tissue.

FIGS. 2C to 2E show cross-sectional side views of rotatable valves which may be used control the vacuum force within the device.

FIGS. 3A and 3B show an end view of a pod assembly which has been translated 15 with respect to one another while adhering tissue.

FIG. 3C shows an end view of a pod assembly in which a single pod member has been actuated with tissue adhered thereto.

FIG. 4 shows a representative illustration of the tissue overlap which is created by 20 the translated pod assembly.

FIG. 5 shows an example of a cross-sectional side view of the tissue overlap where a stapler assembly has been articulated and clamped onto the tissue overlap.

FIG. 6A shows a partial assembly of the handle for the folder assembly.

FIG. 6B shows a detail view of an exploded assembly of anchoring mounts and a 25 proximal portion of an actuation rod assembly.

FIG. 7 shows a side view of an alternative variation on a dual actuator folder assembly housing.

FIGS. 8A to 8C show side, end, and perspective views, respectively, of a link which may serve as a transitional link between the folder handle and the working body.

FIGS. 9A to 9C show side, end, and perspective views, respectively, of one 30 variation of links which may be used to form at least part of the working body.

FIG. 9D shows an end view of a link having cross-sections of some of the various internal lumens which may be routed through the working body.

FIGS. 10A to 10C show side, end, and perspective views, respectively, of one variation of an end link which may be used as a terminal link of the working body.

FIG. 11 shows an end view of a link with the fixation assembly positioned within for advancement through the main lumen of the working body while maintaining a
5 consistent orientation.

FIGS. 12A to 12C show top, cross-sectional side, and perspective views, respectively, of one variation of a yoke member.

FIGS. 12D and 12E show front and rear end views, respectively, of the yoke member of FIGS. 12A to 12C.

10 FIG. 13A shows a top view of a stapler cartridge assembly positioned between the arm members of the yoke.

FIGS. 13B and 13C show variations of the stapler assembly positioned between the yoke having varied open regions.

15 FIGS. 14A to 14C show top, end, and side views, respectively, of an alternative angled hinge member for use with a pod member.

FIGS. 15A to 15C show top and perspective views, respectively, of a variation of a yoke and hinge assembly.

FIGS. 16A to 16C show perspective views of a variation on a hinge device which may be adapted to angle a pod assembly in an offset configuration.

20 FIG. 17A shows a perspective view of one variation of the pod assembly with the top cover and optional basket insert removed for clarity.

FIG. 17B shows a perspective view of one variation of a top cover which may be used with the pod assembly.

25 FIG. 17C shows a cross-sectional view of an optional basket insert positioned within a vacuum chamber and a top cover secured over the chamber.

FIGS. 17D and 17E show another variation of Figs. 17B and 17C, respectively, where the top cover and/or pod member may have serrations.

30 FIGS. 18A to 18D show side, end, bottom, and perspective views, respectively, of an optional basket insert which may be placed within the vacuum chamber of the pod assembly.

FIGS. 19A and 19B show side and top views, respectively, of another variation of the pod assembly where an angled pod assembly may be mounted on a distal end of the working body.

FIGS. 19C and 19D show rear and front views, respectively, of the pod members and the staple assembly of FIGS. 19A and 19B.

FIGS. 20A and 20B show side views of a variation of the stapler assembly in clamped and opened configurations, respectively.

5 FIGS. 21 A and 21 B show side views of a variation of a cam member which may be used to urge the stapler assembly open and close.

FIGS. 22A to 22C show cross-sectional side, front, and top views, respectively, of one variation of stapler assembly.

FIG. 22D shows a top view of the anvil of the stapler assembly.

10 FIG. 22E shows a side view of another variation of a stapler assembly having serrations defined along its clamping surfaces.

FIG. 23A shows a top view of one variation of staple pushers positioned over corresponding staples.

FIG. 23B shows a detailed perspective view of one example of a staple pusher.

15 FIG. 23C shows a perspective view of one example of a wedge which may be configured to slide within the cartridge housing.

FIGS. 24A and 24B show cross-sectional side views of one variation of a stapler handle and its associated controls.

20 FIGS. 25A and 25B show perspective views of another variation of the approximation device having an actively or passively curved working body.

FIG. 25C shows a detail view of the actuation handle of the device in FIGS. 25A and 25B.

FIGS. 25D and 25E show perspective and end views, respectively, of a variation of an end cap or seal which may be used to cap the handle of FIG. 25C.

25 FIG. 26 shows a perspective view of one variation in which an endoscope can be retroflexed to view the results or progress of the tissue approximation and/or fixation.

FIG. 27 shows a portion of a flexible shaft of a stapler assembly with several insertion indicators positioned through the main lumen of the handle of the folder assembly.

30 FIG. 28 shows a perspective view of another embodiment of a fixation assembly.

FIG. 29 shows an elevational view of a stapler assembly of the fixation assembly in a closed configuration.

FIG. 30 shows a perspective view of the stapler assembly in an open configuration.

FIG. 31 shows a partial cross-sectional view of the stapler assembly in the open configuration.

FIG. 32 shows an exploded view of a cross stapler device.

FIG. 33 shows a distal end of the cross stapler device.

5 FIG. 34 shows a partial perspective view of another embodiment of a cross stapler device.

FIGS. 35 through 42 show a cross-sectional view of one method of forming a gastric sleeve and an additional single fold of tissue near a distal stoma of the gastric sleeve to narrow the distal stoma.

10 FIG. 43 shows a schematic view of the single fold of tissue narrowing the distal stoma of the gastric sleeve.

FIG. 44 shows a schematic view of multiple plications placed within the stomach cavity, and single folds of tissue placed within the stomach cavity to narrow the outlets of the gastric sleeves created by the plications.

15 FIG. 45 shows a cross-sectional view taken along line 45-45 of FIG. 44.

FIG. 46 shows a schematic view of an intragastric band secured to the stomach wall and cinched to reduce the volume of the stomach, and multiple single fold plications placed around the intragastric band.

20 FIG. 47 shows a schematic view of an open proximal stoma of a longitudinal plication that is positioned too low in the stomach cavity.

FIG. 48 shows a schematic view of a plication placed to close the open proximal stoma of FIG. 47.

FIG. 49 shows a schematic view of a plication that is angled away from the lesser curve of the stomach.

25 FIG. 50A shows a cross-sectional view taken along line 50-50 of FIG. 49, with dual plications positioned in the distal stoma of the gastric sleeve.

FIG. 50B shows a cross-sectional view taken along line 50-50 of FIG. 49, with a dual fold plication positioned in the distal stoma of the gastric sleeve.

30 FIG. 51 shows a schematic view of a cross stapler device placing a plication within a gastric sleeve.

FIG. 52 shows a cross-sectional view taken along line 52-52 of FIG. 51 without the cross stapler device.

FIG. 53 shows a schematic view of two flaps of tissue placed within a gastric sleeve to act as a valve.

FIG. 54 shows a schematic view of a stapling device positioned to acquire and over-staple an existing longitudinal plication.

FIG. 55 shows a schematic view of a longitudinal plication within a stomach cavity and a laparoscopic band positioned around the outer surface of the stomach.

5 FIG. 56 shows a schematic view of a gastric band placed within a gastric sleeve to narrow the distal stoma.

FIG. 57 shows a schematic view of a surgical clip placed within a gastric sleeve to narrow the distal stoma.

10 FIG. 58 shows a schematic view of two magnets placed within a gastric sleeve to narrow the distal stoma.

FIG. 59 shows a cross-sectional view taken along line 59-59 of FIG. 58.

FIGS. 60 and 61 show a schematic view of a catheter delivering energy to the stomach tissue to shrink the tissue around a distal stoma of a gastric sleeve.

15 FIGS. 62 and 63 show a schematic view of a catheter delivering a bulking agent to the stomach tissue to narrow a distal stoma of a gastric sleeve.

FIG. 64 shows a cross-sectional view of a stomach cavity with an externally placed single fold of tissue near a distal stoma of a gastric sleeve.

Detailed Description of the Preferred Embodiments

A system for tissue approximation and fixation is described which may be utilized 20 for approximating tissue regions from within a hollow body organ, such as the stomach, esophageal junction, and other portions of the gastrointestinal tract. The system may be advanced within a body through a variety of methods, *e.g.*, transorally, transanally, endoscopically, percutaneously, *etc.*, to create one or several divisions or plications within the hollow body organ. At least two devices may be utilized as part of the system, a tissue 25 acquisition and folding system and a tissue stapling or fixation system, although it is contemplated that both devices can be integrated into a single mechanism. Each of these devices may be configured to efficiently operate with one another to provide optimal methods and devices for at least acquiring, approximating, and stapling regions of tissue from within the hollow body organ in a minimally invasive manner.

30 Turning now to the figures, the system will first be described generally in which one variation of system 10 is shown in FIG. 1, which illustrates a perspective view of folder assembly 12 and fixation assembly 14. Folder assembly 12, which is described below in greater detail, may be comprised generally of pod assembly 16, which may be used to initially acquire and approximate the tissue to be folded. Pod assembly 16 may

have a first pod member 18 and a second pod member 20, each of which may be independently articulatable to form a first compact configuration and a second larger, expanded configuration. Each of first and second pod members 18, 20 may be connected to respective first and second actuation rods 22, 24 on the distal end of a yoke member 26, 5 as described in further detail below.

Pod assembly 16 may be located at the distal end of working body 28 which may be configured as a flexible shaft having one or several lumens defined through the length of the working body 28. The working body 28 may be covered by a sheath or covering 30 to enhance the lubricity of the shaft as well as to maintain the interior of the body 28 clear 10 from body fluids and debris and provide a seal to allow insufflation of the target organ. Various materials may be utilized for sheath 30 including various plastics, elastomers, latex, polyurethane, thermoplastics, *e.g.*, PTFE, FEP, silicone, PVC, Tecoflex®, Pebax®, *etc.*, so long as they are preferably biocompatible.

A number of vacuum tubes 32 may also be routed through the length, or a partial 15 length, of the working body 28 to pod assembly 16. The figure shows vacuum tubes 32 entering the working body 28 at its proximal end. Alternatively, vacuum tubes 32 may enter working body 28 at some distal point along the length of body 28 or vacuum tubes 32 may enter working body 28 through handle 34. In either case, vacuum tubes 32 may be positioned within one or several lumens defined through working body 28 and placed in 20 fluid communication with respective first and second pod members 18, 20 to facilitate in vacuum actuation of tissue, as further described below. The proximal ends of vacuum tubes 32 may be connected to one or more vacuum pumps (not shown). Furthermore, vacuum tubes 32 may utilize braided materials, *e.g.*, stainless steel, superelastic materials such as Nickel-Titanium alloy, integrated throughout to prevent kinking or pinching of the 25 tubes 32. Such vacuum tubes 32 may also accommodate insertion of a snare or grasper type device that can be inserted once tissue is acquired to mechanically grasp the invaginated tissue, depending on the type of tissue manipulation desired. An example of a "gooseneck" snare by Microvena, Inc. which may be used with the vacuum tubes 32 is described in further detail in U.S. Pat. No. 5,171,233, which is incorporated herein by 30 reference in its entirety.

The proximal end of working body 28 is operatively connected to handle 34. Also connected to handle 34 are first and second actuators 36, 38 which may be used to actuate first and second pod members 18, 20, respectively, from the first compact configuration to the second larger, expanded configuration. Each actuator 36, 38 may be actuated

individually to control a corresponding pod member independently of the other pod member or may be actuated simultaneously, as described later herein. Main lumen 40 may be defined throughout the length of working body 28 and through handle 34 such that fixation assembly 14 may be advanced and withdrawn through the folder assembly 12.

5 Fixation assembly 14 comprises, in part, stapler assembly 42 connected via flexible shaft 48 to a stapler handle 50. Stapler assembly 42 generally comprises staple cartridge 44, within which one or more staples are housed. Stapler assembly 42 may also have an optional tapered distal end to facilitate insertion of the device into or past tissue, as described in further detail below. Anvil 46 is in apposition to staple cartridge 44 and is

10 used to provide a staple closure surface when tissue to be affixed is adequately positioned between staple cartridge 44 and anvil 46. With stapler assembly 42 connected at the distal end of flexible shaft 48, handle 50 is connected at the proximal end of shaft 48. Handle 50 may generally comprise a housing and grip 52 in apposition to actuation handle 54. Handle 50 allows for the surgeon or user to hold and manipulate fixation assembly 14 with

15 grip 52 while articulating stapler assembly 42 between an open and close configuration via actuation handle 54. Moreover, the configuration of handle 50 allows the surgeon or user to articulate stapler assembly 42.

When fixation assembly 14 is advanced within folder assembly 12, stapler assembly 42 is preferably in a closed configuration. When stapler assembly 42 has exited working body 28, staple cartridge 44 may be articulated into an open configuration when positioned between yoke 26 to receive the tissue folded between pod members 18, 20. Stapler assembly 42 may then be advanced distally over the folded tissue and clamped close over the tissue for deploying the staples. To avoid damaging tissue surrounding pod assembly 16 and to facilitate proper stapling, one or several insertion indicator(s) 56 may be defined along a portion of flexible shaft 48 preferably near a proximal end of shaft 48, to aid the user in knowing when stapler assembly 42 may be safely articulated while fixation assembly 14 is positioned within working body 28. Indicators 56 may be configured to align with a proximal end of folder handle 34 to correspondingly indicate, e.g., a position of fixation assembly 14 relative to folder assembly 10 when stapler assembly 42 may be opened, and/or how far distally fixation assembly 14 may be advanced relative to folder assembly 10 to engage the folded tissue, etc. In addition to visual indicators, a mechanical indication, such as a stop or detent may be employed to give the operator a tactile indication of "safe to open" and "safe to clamp" device positions.

A brief description of the pod assembly 16 will be given in order to describe how the tissue may be manipulated by the devices described herein. A more detailed description will be given below. Side and top views of one variation of pod assembly 16 is shown in Figs. 2A and 2B, respectively. Pod members 18, 20 may each be comprised of a
5 vacuum chamber or opening 60 into which tissue may be drawn therewithin. A vacuum tube 76 may be seen in FIG. 2A leading to first pod member 18. The opening of vacuum chamber 60 may be slotted along a direction parallel to a longitudinal axis of the working body 28, or may be transverse to the parallel axis; alternatively, the opening may be defined a variety of shapes, *e.g.*, oval, elliptical, *etc.* Adjacent to and preferably parallel
10 with vacuum chamber 60 is tensioning arm or member 62, which may have a length equal to that of vacuum chamber 60. Alternatively, a length of tensioning member 62 may be less than or greater than that of vacuum chamber 60. The distal end of each pod member may have a flexible and/or atraumatic tip 64, 66 made from any number of polymers to facilitate the guidance of pod assembly 16 into the hollow body organ without damaging
15 tissue along the way.

A guidewire may optionally be used with the folder assembly 12 during initial deployment and positioning within the hollow body organ in a manner similar to a catheter for guiding pod assembly 16 to a predetermined position. Accordingly, an optional guidewire lumen may be defined in one or both atraumatic tips 64, 66; as seen in tip 64,
20 guidewire lumen 68 may be defined therein with guidewire 80 extending through from proximal guidewire opening 70 to distal guidewire opening 78. Proximal and distal guidewire openings 70, 78, respectively, may both be defined on, *e.g.*, atraumatic tip 64, to enable exchange of the guidewire through one or both tips; however, guidewire openings 70, 78 may also be defined on other regions of pod members 18, 20 depending upon the
25 type of exchange capability desired.

Both first and second pod members 18, 20 may each be adapted to pivot on respective hinge members 72, 74 such that in a first compact configuration, first and second pod members 18, 20 may be immediately adjacent to one another. As shown, first pod member 18 has a corresponding tensioning member 62 aligned adjacent to member 18
30 and second pod member 20 has a corresponding tensioning member 90 also aligned adjacent to member 20. In moving to a second expanded configuration, pod member 18 with tensioning member 62 and pod member 20 with tensioning member 90 may be translated via actuation rods 22 into opposing radial directions from one another relative to yoke 26, as shown in FIG. 2B.

The vacuum force which may be used to draw in the tissue may be controlled through a number of various methods. One variation is illustrated in Figs. 2C to 2E, which show how valves 82 may be integrated into handle 34 for controlling the vacuum force. As seen in the cross-sectional side view of FIG. 2C, valve 82 may be configured to rotate 5 and align such that vacuum lumen 84 comes into fluid communication with lumen 86, which leads to working body 28. Vacuum lumen 84 may be connected to a vacuum control unit (not shown), *e.g.*, a standard luer assembly (QOSINA, model # 99720), to allow for air to be drawn through lumen 86 and create the vacuum at the distally-located pod members. FIG. 2D shows how valve 82 may be rotated by some degree, *e.g.*, 45° 10 relative to a longitudinal axis of handle 34, such that the vacuum force is no longer in fluid communication with lumen 86. FIG. 2E shows how valve 82 may be further rotated, *e.g.*, 90° relative to a longitudinal axis of handle 34, such that lumen 86 is in fluid communication with venting lumen 88 to allow for venting of the assembly. A second valve, as shown, may be integrated in handle 34 to allow for the independent control of the 15 vacuum force in the second pod member. Each of the vacuum lumens 84 may be fluidly connected to a common or independent vacuum pump. Moreover, rather than having two independently controllable valves 82, a single valve 82 may be utilized to control the vacuum force in both pod members, depending upon the desired results. The above variations are intended to be illustrative and are not intended to be limiting in their scope 20 of the disclosure in the various possible configurations and methods available for controlling the vacuum force.

Figs. 3A and 3B show the movement of pod members 18, 20 relative to one another in reconfiguring the surrounding tissue. FIG. 3A shows an end view of pod members 18, 20 which have been advanced while in a closed configuration into, *e.g.*, a 25 stomach, and positioned adjacent to a region of interior tissue to be reconfigured. When desirably positioned, a vacuum force may be applied within one or both pod members 18, 20 such that tissue begins to enter within one or both of the vacuum chambers or openings 60, 92.

The different linings of the stomach, which include the mucosal layer MUC, 30 muscular layer ML, and serosal layer SL, are shown in cross-section. The vacuum force may be applied such that at least the mucosal layer MUC of opposing portions of tissue, *e.g.*, an anterior wall AW and posterior wall PW, are drawn into vacuum chambers 60, 92 and the tissue is sufficiently adhered to the pod members 18, 20. While the vacuum force is applied, pod members 18, 20 may be translated away from one another in opposing

direction such that the adhered tissue is drawn between each pod member 18, 20 and respective tensioning member 62, 90 such that at least two adjacent folds of tissue are created to form an overlap region of tissue, as shown in FIG. 3B. Alternatively, rather than having both pod members 18, 20 move opposite to one another, one pod member may 5 be held stationary while the other pod member is translated radially. In addition, it may be desirable to acquire tissue and translate a first pod, and subsequently acquire tissue and translate a second pod as a separate step to enhance tissue acquisition and positioning. After the tissue has been acquired through any of the methods described above, the device may be curved or manipulated, as described in further detail below. The tissue may then 10 be affixed through one of the methods as described herein.

Similarly, it may be desirable to actuate only one pod and tensioning member to acquire a single, longitudinal fold, for use in treatments such as GERD or to exclude certain portions of the wall of the body organ. Examples of other treatments are described in further detail in co-pending U.S. Pat. App. Serial No. 10/417,790, which has been 15 incorporated by reference above. Accordingly, similar to the tissue acquisition in FIG. 31B, FIG. 3C shows how the device may be utilized for acquiring and tensioning a single layer of tissue. In such an acquisition, the vacuum force may be simply shut or turned off in one of the pod members, in this case, pod member 18 while the vacuum force in pod member 20 may remain activated.

FIG. 4 shows a representative illustration of the tissue overlap which is created by 20 the devices, as described herein. The devices are removed for clarity to better illustrate the tissue overlap formation. FIG. 5 shows an example of a cross-sectional side view of tissue overlap 100 where staple cartridge 44 and anvil 46 have been articulated and clamped onto overlap 100 for stapling. When the tissue overlap 100 is created by folder assembly 12, 25 overlap 100 preferably includes an overlap of at least the muscular layer ML and serosal layer SL to ensure a secure anchoring platform for the staples or fasteners to maintain the durability of the tissue overlap 100. A more detailed discussion may be found in U.S. Pat. App. Serial No. 10/188,547 filed July 2, 2002 and entitled "Method And Device For Use In Tissue Approximation And Fixation", which is incorporated herein by reference in its 30 entirety.

FOLDER ASSEMBLY

Folder assembly 12 may typically comprise a handle 34 at a proximal end of the assembly 12, as described above. Handle 34 may comprise housing 110 which may enclose a pod actuation assembly within. FIG. 6A shows a partial assembly of handle 34

to illustrate the internal mechanisms. As described above, first actuator 36 may be used to manipulate first pod member 18 from a first configuration to a second configuration. Pod manipulation may be achieved, in part, by having first actuator 36 connected via shaft 112 to transmit a torquing force to threaded carriage shaft 114. The carriage shaft 114 is 5 preferably free-floating, *i.e.*, can translate longitudinally inside the shaft 112. Proximal mount 116 may be free to rotate about the carriage shaft 114, but it is preferably constrained to inhibit translation of mount 116 relative to the carriage shaft 114. Distal mount 118 may be slidingly positioned over carriage shaft 114, typically by a threaded connection. This threaded connection maintains a fixed relative distance between the 10 mounts so that the mounts and the carriage shaft 114 may translate longitudinally as a unit. Proximal mount 116 and distal mount 118 may be anchored to the proximal ends of the actuation rod and tubing member, which houses the actuation rod, as described further below. Each mount 116, 118 and shaft 112 may be configured to be free-floating, *i.e.*, translate longitudinally unconstrained, inside of shaft 112 within first actuation channel 15 120 to accommodate the lateral movement of working body 28 and the subsequent translational movement of the proximal ends of actuation rods within housing 110. Stop 144, *e.g.*, a ring or shoulder defined upon shaft 114, may be positioned proximally of mount 116 to prevent the longitudinal movement of mount 116 along shaft 114. Mounts 116, 118, however, maybe configured to maintain a fixed distance relative to one another 20 when longitudinally translated as a unit. Corresponding mounts may be configured to translate along a second shaft (not shown) within second actuation channel 122 for a second actuation rod. Mounts 116, 118 may thus translate as a unit until actuator 36 is rotated.

The handle mechanism 34 helps to ensure that relative or unwanted movement of 25 the pods during flexing of the shaft of the folder is minimized or eliminated. Additionally, tubes 136, as further described below, function so that the shaft of the device is not loaded during actuation. These tubes 136 help to support the actuation load, but still allow sufficient shaft flexibility.

As shown in FIG. 6B, which is a detail view of an exploded assembly of mounts 30 116, 118 and their corresponding actuation rod assembly. Proximal mount 116 may have a rod anchoring region 130 defined along one side and distal mount 118 may have tubing anchoring region 132 defined along one side and collinearly with rod anchoring region 130. Actuation rod 140 may be slidingly positioned within tubing member 136 and configured to slide longitudinally therewith when translated relative to tubing member

136 for actuating a pod member. Actuation rod 140 may be anchored to proximal mount 116 by securely positioning actuation rod anchor 142 within anchoring region 130. Likewise, tubing member 136 may be anchored to distal mount 118 by positioning tubing anchor 138 within tubing anchoring region 132. Each mount 116, 118 may have 5 collinearly defined openings 134 to accommodate rod tubing 136 and actuation rod 140 when they are secured within anchoring regions 130, 132. As actuator 36 is rotated, carriage shaft 114 is rotated about its longitudinal axis to urge mount 118 towards or away from mount 116, as shown by the arrows, depending upon which direction carriage shaft 114 is rotated. When mounts 116, 118 are urged towards one another, actuation rod 140 is 10 forced to slide distally within and relative to tubing 136 to urge the pod member, *e.g.*, into its expanded configuration. Similarly, when mounts 116, 118 are urged away from one another, actuation rod 140 is forced to slide proximally within and relative to tubing 136 to urge the pod member, *e.g.*, into its compact configuration.

As further seen in FIG. 6A, main lumen 40 may be defined through a length of 15 housing 110 to accommodate insertion of the fixation assembly 14 therethrough. The proximal opening 128 of lumen 40 may be gasketed to allow for the insufflation of the hollow body organ using the device as well as to prevent the leakage of bodily fluids and particles. Distal opening 124 may likewise be gasketed and is further configured to accept a proximal end of working body 28. The individual links 126 of one variation of the 20 proximal end of working body 28 are shown in the figure to illustrate an example of the mating between working body 28 and housing 110.

An alternative variation on the folder assembly housing is shown in dual actuator assembly 150 in FIG. 7. In this variation, a side view of housing 152 is seen in which a single actuator or lever 158 may be utilized to manipulate both pod members 25 simultaneously. Lever 158 may be configured to rotate about pivot 160 to urge actuation link 162 to translate within actuation slot 164 to simultaneously manipulate both pod members rather than having two or more separate controls. The proximal end of working body 154 may be seen connected to housing 152 and vacuum tube 156 may be seen leading into working body 154 for communication with the folder assembly.

When lever 158 is depressed, actuation link 162 translates proximal linkage 155 within actuation slot 164. Proximal linkage 155 is free to rotate about a pivot during flexure of the working body 154 and actuates proximal blocks 153 to slide longitudinally within channels 151, which are defined through housing 152. A spring or biased element 168 may be positioned within slot 164 to place a biasing force on link 162 and lever 158

such that the assembly maintains a neutral or fixed orientation, if desired. Proximal blocks 153 are connected to actuation rods 157 which may extend distally through distal blocks 159 and further into working body 154. Distal blocks 159 may be pivotally connected to distal linkage 163, which may be pivotally affixed to housing 152 via pivot 166 while 5 allowing distal blocks 159 to translate within channels 151. Tubing members 161 may be configured to allow passage of actuation rods 157 therethrough while remaining connected to distal blocks 159. Although the specific configuration of this variation is shown and described, this is not intended to be limiting and is illustrative of one variation of a handle which allows for single activation and tunable mechanical advantage.

10 The working body 28, which extends between the handle and the pod assembly located at the distal end of the working body 28, may be comprised of a plurality of links or knuckles generally cylindrical in shape and positioned adjacently to one another, as shown and described above in FIG. 6A. A transition link or knuckle 170 is shown in Figs. 8A to 8C, which show side, end, and perspective views, respectively, of a link which may 15 serve as a transitional link between the handle and the length of the working body 28. As seen in the side view of FIG. 8A, transition link 170 may have a proximally located cylindrically-shaped flange 172 with a diameter greater than a diameter of the body portion 176. Flange 172 may serve to help anchor the working body 28 to the handle by fitting within a cavity defined in the handle and shaped to receive flange 172. A transition portion 174 may taper a region of the link 170 down to body portion 176. The end view in 20 FIG. 8B shows main lumen 178 defined through the length of link 170. Main lumen 178 may be shaped with parallel sides opposite to one another to allow fixation assembly therethrough in a specified configuration, as described below in further detail.

Although the transition link 170 is shown to be generally cylindrical in shape, it 25 may alternatively be configured in a variety of shapes, *e.g.*, ovular, elliptical, *etc.* Transition link 170 may also range in diameter, *e.g.*, 0.75 in. (about 1.90 cm), so long as it is wide enough to accommodate the insertion of fixation assembly 14 therethrough yet small enough to be inserted into the body, *e.g.*, through the esophagus. Link 170 may also range in length, *e.g.*, 1.125 in. (about 2.85 cm), depending upon the desired design 30 characteristics. Moreover, transition link 170 may be made from a variety of materials, *e.g.*, metals, plastics, *etc.*, so long as it is biocompatible. For example, transition link 170 may be made from stainless steel, nickel-titanium alloys, or it may be molded from plastics and thermoplastics, *e.g.*, polycarbonate resins such as Makrolon® (Bayer Aktiengesellschaft, Germany).

Figs. 9A to 9C show side, end, and perspective views, respectively, of an example of a knuckle or link 180 which may be used to form at least part of the working body 28. This link variation 180 may be made from a material similar to that of transition link 170. It may also range in diameter, *e.g.*, 0.69 in. (about 1.75 cm), so long as link 180 is wide enough to accommodate the insertion of fixation assembly 14 therethrough yet small enough to be inserted into the body, as above. Lumen 182 may be configured such that it is keyed to allow fixation assembly 14 to pass through in a specified configuration; thus, in this particular variation, lumen 182 is shown as having straight walls 196, which may be parallel and opposite to one another. Link 180 may also define one or more routing channels 184 around the circumference of the link 180 to allow for the routing of various wires or tubes therethrough along a length of working body 28. Link 180 shows a variation in which two routing channels 184 may be defined on opposing sides around the circumference. As further seen in FIG. 9A, link 180 may further define peripherally located actuator rod lumens 196 and additional routing lumens 188 in link 180 outside of lumen 182. This variation shows at least two of each lumen 186, 188 defined on opposing sides of link 180, although they may be defined elsewhere around link 180 in other variations depending upon the number of lumens desired as well as spacing considerations.

FIG. 9B shows a side view of link 180 having least two protrusions 190 extending from a first surface 192 on either side of the periphery of link 180. Protrusions 190 may extend from first surface 192 at a distance, *e.g.*, 0.040 in. (about 0.10 cm), so that when multiple links are aligned with one another, protrusions 190 abut the second surface 194 of an adjacent link, as shown in FIG. 9C. When multiple links are aligned, lumen 182, as well as actuator rod lumen 186 and additional routing lumen 188 may be aligned with adjacent links to form the overall main lumen 40 and actuator rod lumen, as described above. Alternatively, overall flexibility of the device may be achieved by a single structure that contains axial slots along its length, such as that shown in U.S. Pat. No. 5,685,868, which is incorporated herein by reference in its entirety. Similarly, the working body may be formed of a single piece, flexible component, such as a polymer extrusion and/or multi-lumen co-extruded design, a braid, or other such known materials.

FIG. 9D shows an end view of link 180 in one variation where actuation rod 198 is routed through actuator tubing member 202 and both may be disposed within actuator rod lumen 186 such that both extend through a length of working body 28. Vacuum tubes 200 may also be positioned within routing channels 184 and the entire assembly may be covered by sheath or lining 204, which may extend along at least a portion of working

body 28, and preferably over the entire length of working body 28. Sheath or lining 204, as mentioned above, may be used to enhance the lubricity of the working body 28 as well as to maintain the interior of the body 28 clear from body fluids and debris and to provide sealing to enable insufflation of the target area. Various materials may be utilized for 5 sheath 204 including various plastics, elastomers, latex, polyurethane, thermoplastics, *e.g.*, PTFE, silicone, PVC, FEP, Tecoflex®, Pebax®, *etc.*, so long as they are preferably biocompatible. Moreover, sheath 204 may also utilize braided materials integrated throughout to increase tensile, compressive, and/or torsional strengths of sheath 204 as well as to provide for resistance against kinking or pinching between individual links or 10 when working body 28 is flexed.

FIGS. 10A to 10C show side, end, and perspective views, respectively, of one variation of end link 210, which may be utilized as the terminal or final link of working body 28. End link 210, much like links 180, may define a keyed lumen 212, routing lumens 214, and actuator rod lumen 218. Lumen 216 may also be defined and it may be counterbored to accommodate a mechanical fastener for connecting the yoke member. As 15 the terminal link, actuator tubing member 202 may be terminated and attached to end link 210 at lumen 218 while allowing the actuator rod to extend through and beyond lumen 218 for attachment to the pod assembly. Side and perspective views in FIGS. 10B and 10C further show detent 222, which may be defined along the end surface of link 210 for 20 receiving and/or engaging the yoke member. Moreover, end link 210 may be made from the same or similar materials as described above for the other links. However, end link 210 is preferably made from a material such as a metal, *e.g.*, stainless steel, or polycarbonate, which may withstand forces generated during pod and tissue manipulation. The end link 210, or a similar or additional link, may also be used to terminate any 25 covering placed over the working body 28 as heretofore described in FIG. 9D.

FIG. 11 shows an end view of link 180 with staple cartridge 44 and anvil 46 of fixation assembly 14 positioned within lumen 182 for advancement through working body 28. As seen, lumen 182 may be configured such that it is keyed to allow fixation assembly 14 to pass through in a specified orientation. Walls 196, which may be parallel and 30 opposite to one another, may thus be sized and configured to prevent fixation assembly 14 from rotating about its own longitudinal axis within lumen 182 during advancement and deployment from the main lumen. Maintaining fixation assembly 14 in a predetermined orientation relative to working body 28 and pod assembly 16 also helps to ensure that when staple cartridge 44 and/or anvil 46 are actuated to open for clamping over folded

tissue, a known orientation of fixation assembly 14 relative to the folded tissue is maintained for tissue fixation. Other configurations for keying lumen 182 to fixation assembly 14 may be available in other variations; the shape of lumen 182 and the cross-sectional shape of fixation assembly 14 are not intended to be limiting but are merely 5 illustrative of one possibility of creating and/or configuring a keyed orientation between the two assemblies.

A yoke member may be positioned at the terminal end of working body 28 for holding and maintaining pod assembly 16. FIGS. 12A to 12C show top, cross-sectional side, and perspective views, respectively, of yoke 230. Generally, yoke 230 may be 10 comprised of first arm member 232 and second arm member 234 extending in parallel to one another from a base member 242, which may be attached via proximal surface 244 to end link 210 of working body 28. Yoke 230 may terminate at each arm member 232, 234 in first and second pivot regions 236, 238, respectively, about which the pod assembly 16 may be manipulated. First and second arm members 232, 234 may further extend 15 longitudinally with an overall length of about, e.g., 2 in. (about 5 cm), to create open region 240 between the arm members 232, 234. First and second arm members 232, 234 may also be tapered along their lengths to facilitate insertion of yoke 230 within a tissue region. The opposing sides of each arm member 232, 234, which in part defines open region 240, may be parallel to one another and are spaced apart, e.g., at 0.40 in. (about 1.0 20 cm), to provide clearance for stapler assembly 42 to be advanced therethrough. Furthermore, the open sides of region 240 may provide adequate clearance for stapler assembly 42 to be opened for advancement over tissue to be affixed while arm members 232, 234 help to maintain the orientation of stapler assembly 42 relative to yoke 230 and working body 28.

25 The actuation rods for manipulating pod assembly 16 may extend through yoke 230 via first and second actuation rod channels 246, 248, which may be seen in the perspective view of yoke 230 in FIG. 12C. A portion of actuation rod channels 246, 248 may be slotted or grooved and open along an outer surface of each of arm members 232, 234 to allow actuation rods to extend past the outer surface during pod manipulation. Figs. 30 12D and 12E show front and rear end views, respectively, of yoke 230 to provide a detail view of actuation rod channels 246, 248 and open region 240.

As mentioned above and as shown in the top view of stapler cartridge/yoke assembly 250 in FIG. 13A, each arm member 232, 234 may be parallel to one another and spaced apart to provide clearance for stapler assembly 42 to be advanced therethrough. The

arm members 232, 234 may function as guide surfaces 252, 254, respectively, to maintain stapler assembly 42 oriented in a predetermined configuration relative to yoke 230. Furthermore, open region 240 may provide adequate clearance for stapler assembly 42 to be opened prior to advancement over tissue while guide surfaces 252, 254 help to maintain
5 the orientation of stapler assembly 42 relative to yoke 230 and working body 28. Additionally, as shown in FIG. 13A, clearance slots (open region 240) may function to provide clearance for an endoscope or other tool, that can be inserted and advanced or retroflexed to view the working device, as shown below in further detail. To assist in alignment of the stapler assembly 42 to the target tissue, it may be desirable to vary the
10 length of the open region 240. As further shown in FIG. 13B, open region 240 may be configured with a stop, cover, or extension 256 located adjacent to anvil 253 to constrain any transverse or lateral movement of anvil 253 while facilitating movement of cartridge assembly 251. Alternatively, if anvil 253' is configured to move, stop or extension 258 may be configured adjacent to cartridge assembly 251' to constrain any transverse or
15 lateral movement of cartridge assembly 251' while facilitating movement of anvil 253', as shown in FIG. 13C.

From the distal end of each arm member 232, 234 of yoke member 230, a hinge member may be connected pivotally and extend distally where it may be again pivotally connected to a pod member. An alternative angled hinge member 260 may be seen in
20 FIGS. 14A to 14C, which show top, end, and side views, respectively. Angled hinge 260 may have a proximal portion 262 connected to a distal portion 264, which may be angled with respect to either or both side surface 270 and top surface 272 of proximal portion 262. A yoke-hinge pivot 266 may be defined at a proximal end of proximal portion 262 for pivotal connection to first pivot 236 located on yoke 230. Similarly, a hinge-pod pivot 268
25 may be defined at a distal end of distal portion 264 for pivotal connection to a pod member. Additionally, actuator rod channel 274 may be optionally defined along at least a portion of proximal portion 262 to provide a opening or space for placement of an actuator rod. A second hinge member, which may mirror the configuration of angled hinge 260, may be configured for connection to second hinge 238 of yoke 230 for connection to a
30 second pod member. Moreover, angled hinge member 260 may be made from any variety of metals or thermoplastics, as described above.

Alternatively, a variation of a yoke/hinge assembly 280 may be utilized, as shown in the top views of FIGS. 15A and 1513. In this variation, yoke/hinge assembly 280 may be configured to flex via one or several additional pivots along its length. Additional ramp

members 286, 286', 290, 290', which may be extension members of yoke 282 having pivoted regions at both proximal and distal ends, may be joined via pivots 284, 284', 288, 288', respectively, to one another to form elongated arms. Hinge members 294, 294' may be connected via pivots 292, 292', respectively, to ramp members 290, 290', respectively, 5 and have pivots 296, 296' located at their distal ends for connection to pod members.

Hinge members 294, 294' may be actuated to an expanded configuration, as shown in FIG. 15A, and yoke/hinge assembly 280 may also be configured to flex via tensioning members (not shown) positioned within a lumen or slot defined along the length of assembly 280 in one or both arms. These tensioning members may be actively 10 manipulated by the user from their proximal ends. Thus, assembly 280 may be flexed to have a bend radius, as shown in the example of FIG. 15B, to allow access to various regions within the hollow body organ as well as to affix various configurations of tissue. Alternatively, assembly 280 may also be passively flexed by contact against tissue or via 15 an external device, such as a mandrel, a gripping tool, or endoscopes configured to flex the assembly 280. FIG. 15C shows an example of a compact configuration of assembly 280 which may be utilized for deployment within a body.

FIGS. 16A to 16C show yet another variation on a hinge device which may be adapted to actively angle the pod assembly in an offset configuration. The working body, as well as vacuum tubes and other features, have been omitted only for the sake of clarity 20 in these views. FIG. 16A shows a perspective view of offset pod assembly 300 in a "straight" configuration where first pod member 302 and second pod member 304 are in a compact or deployment configuration. FIG. 16B shows an example of offset pod assembly 300 in an expanded configuration where first and second pod members 302, 304, respectively, may be actuated to spread apart from one another. First tensioning member 25 or arm 306 may be seen as being part of first pod member 302 and second tensioning member or arm 308 may be seen as being part of second pod member 308.

Offset pod assembly 300 also includes variations on first and second hinge members 310, 312, respectively, which may have respective first and second actuation slots 322, 324 defined longitudinally along a portion of their respective hinge members 310, 312. First actuation linkage 314 may be pivotally connected at its distal end to first pod member 302 and pivotally connected to first hinge member 310 at its proximal end via pivots 318. The proximal end of actuation linkage 314 may also be configured to translate within first actuation slot 322 when urged. Likewise, second actuation linkage 316 may be pivotally connected at its distal end to second pod member 304 and pivotally connected to

second hinge member 312 at its proximal end via pivots 320. Also seen are first and second vacuum openings 326, 328, respectively, for acquiring tissue to be approximated, and first and second vacuum passages 330, 332, respectively.

FIG. 16C shows offset pod assembly 300 having been urged into its offset configuration. As shown, the proximal end of first actuation linkage 314 has been translated distally within first actuation slot 322 and the proximal end of second actuation linkage 316 has also been translated distally within second actuation slot 324. Each linkage 314, 316 may be translated a distance, d , via actuation rods to rotate first and second pod members 302, 304 about their respective pivots such that pod members 302, 10 304 may be offset at an angle, α , relative to a longitudinal axis of the working body. From this offset configuration, tissue may be approximated and affixed at various angles. Alternatively, the pod members 302, 304 may also be configured to be passively flexed by contact against tissue or via an external device, including any of the tools described above. Although both pod members 302, 304 are shown in this illustration as having been offset 15 at similar angles, a single pod member may be alternatively actuated to become offset relative to the other pod member. Furthermore, both pod members may also be offset at various angles depending upon the desired tissue configuration; moreover, each pod member may be also independently offset at its own angle, again depending upon the tissue configuration. These examples are merely intended to be illustrative and are not 20 intended to be limiting.

The pod assembly itself may be seen in greater detail in the perspective view of FIG. 17A. As shown, the pod member may have an elongated vacuum chamber 340. A top cover and an optional basket insert have been removed for clarity. The vacuum chamber 340 may be in fluid communication via vacuum tubes 200 which may be connected to a vacuum pump (not shown) at its proximal end and to vacuum chamber 340 at its distal end. Tensioning member or arm 342 may extend longitudinally adjacent to vacuum chamber 340 while forming a gap between the two through which the tissue may be drawn. The tensioning member 342 may extend along the entire length of the pod member and beyond or it may extend just partially. Alternatively, in other variations, 25 tensioning member 342 may be omitted entirely. In either case, a distal tip of the tensioning member 342 is preferably configured to be atraumatic, e.g., blunted, rounded, or it may have a separate soft tip attached and/or may be shaped or made of a material to conform to the distal esophagus and/or proximal stomach to allow ease of insertion and lessen trauma once in place.

A pivot 344 may be configured at the proximal end of the pod member for attachment to a hinge member. The distal end of the pod member may also have a tapered flexible tip 346 attached thereto. This tip 346 may be configured to have an atraumatic tip 354 to facilitate deployment of the device with minimal damage to the tissue. Flexible tip 5 346 may be made from any variety of biocompatible polymers and elastomers. Flexible tip 346 may also define a guidewire lumen 348 extending from a distal guidewire opening 350 at atraumatic tip 354 to proximal guidewire opening 352 located proximally on flexible tip 346. As mentioned above, a guidewire may optionally be used to guide the pod members during initial deployment and positioning within the hollow body organ in a 10 manner similar to a rapid-exchange (RX) type catheter. Accordingly, an optional guidewire may be passed through guidewire lumen 348 and subsequently removed, if desired. A flat mating surface 356 may also be defined along the side of flexible tip 346 to allow for a compact configuration when the second pod member is positioned adjacently. Tip 354 may be optionally formed of a radio-opaque material or imbued with radio-opaque 15 capabilities.

A top cover 372 which defines opening 374, as shown in FIG. 17B, may be secured over vacuum chamber 340. An undercut 358 may be defined around opening 374 to help aid in mechanically adhering any tissue which may be drawn into opening 374. Opening 374 is shown as being slotted; however, it may be formed into an elliptical shape or 20 various other shapes so long as an adequate opening is available for adhering a sufficient amount of tissue therewithin or thereto. Alternatively, rather than a single opening 374, multiple smaller openings may be defined over top cover 372 so long as an adequate area is available for adhering tissue thereto. An optional mesh-like insert may be positioned within vacuum chamber 340 to help prevent the vacuum chamber from becoming clogged 25 by tissue.

Turning to FIGS. 18A to 18D, an optional basket insert 360 is shown in side, end, bottom, and perspective views, respectively. Basket insert 360 may be placed within vacuum chamber 340 to provide for an optimized mesh surface through which a vacuum force may be applied to the tissue. Overall dimensions of basket insert 360 may vary so 30 long as it may be securely positioned within vacuum chamber 340. An example of insert 360 dimensions is 1.3 in. (about 3.3 cm) in length and 0.3 in. (about 0.8 cm) in width. Basket insert 360 may also be made from a variety of materials, *e.g.*, stainless steel, provided that the tensile strength is sufficient to withstand the various forces generated.

Basket insert 360 may have basket walls 362 forming a mesh-like vacuum chamber 370 with flange 364 surrounding the edges of one open side of insert 360. Each of the basket walls 362 may define a plurality of openings therethrough and the bottom surface of basket walls 362 may also define a plurality of supports 366 positioned in-between 5 openings 368. These supports 366 may be configured to space each of the basket walls 362 away from the walls of vacuum chamber 340, as shown in FIG. 17C, which shows a cross-sectional view of basket insert 360 positioned within vacuum chamber 340 and top cover 372 placed over the chamber 340. Plenum 376 may thus be defined around the entire basket insert 360, or a portion thereof, between basket walls 362 and vacuum 10 chamber 340 via the spacing provided by supports 366 and flange 364. The open plenum 376 allows a vacuum force to be applied to the tissue while preventing the tissue from clogging the vacuum chamber 340.

Alternatively, rather than utilizing a separate basket insert 360 for placement within 15 vacuum chamber 340, the interior surface of vacuum chamber 340 may be textured, channeled, labyrinthined, or interdigitated to increase the surface area for vacuum adherence in the same manner as basket insert 360. Moreover, mechanical tines or teeth may be formed within basket insert 360 or within vacuum chamber 340 to facilitate additional 20 mechanical adherence of tissue within the pod member. Another alternative may utilize a snare-like wire or member positioned within vacuum chamber 340 around opening 374. In such a variation, once tissue has been drawn through opening 374, the snare may be drawn tightly around the adhered tissue.

Moreover, one or both pod members may also incorporate a number of other methods to facilitate tissue movement and/or adherence to the respective pod member. For instance, FIGS. 17D and 17E show the top cover 372 and cross-sectional view of basket 25 insert 360, respectively, of FIGS. 17B and 17C with the addition of serrations 341. These serrations 341 are shown as being defined along a length of cover 372; however, they may alternatively be defined around the opening 374 or in a number of various other configurations depending upon the desired results. Furthermore, serrations 341 are illustrated as protrusions but any variations or configurations of serrations 341 may also be 30 utilized in other variations of the device.

FIGS. 19A and 19B show another variation of the pod assembly where angled pod assembly 380 may be mounted on a distal end of working body 382. As shown, first and second pod members 384, 386, respectively, may be configured to extend angularly via angled hinges 260. Also shown are vacuum tubes 388 extending between pod members

384, 386 and working body 382. The figures also show the positioning of staple cartridge 44 and anvil 46 opened for clamping onto folded tissue, which is not shown for clarity. FIGS. 19C and 19D show rear and front views of pod members 384, 386 and staple cartridge 44 and anvil 46.

5 **FIXATION ASSEMBLY**

The fixation assembly, as mentioned above, may be delivered through the main lumen of the folder assembly for deployment over tissue which has been approximated into a folded configuration. One variation of a stapler which may be used with the folder assembly described herein is described in detail in U.S. Pat. No. 4,610,383 (Rothfuss et al.), which is incorporated herein by reference in its entirety. Another variation of a stapler assembly 390, which is positioned at the distal end of the fixation assembly, is shown in side views in FIGS. 20A and 20B. Generally, stapler cartridge 392 may be pivotally connected via pivot 396 to the end of flexible shaft 398. Anvil 394 may be configured to remain stationary relative to flexible shaft 398 while stapler cartridge 392 may be manipulatable into an open and closed configuration with respect to flexible shaft 398 and anvil 394. As seen, stapler cartridge 392 and/or anvil 394 may optionally incorporate a tapered end 411 positioned at a distal end of either cartridge 392, anvil 394, or both. Tapered end 411 may be fabricated of any of the polymers or other materials described herein and is preferably atraumatic to facilitate dilation or insertion past tissue. To manipulate stapler cartridge 392 to open and close, a circular or disk-shaped cam 400 may be pivotally attached about rotational pivot 402 located on the side of the proximal end of stapler cartridge 392. As seen in the detail view of cam 400 in FIG. 21A, actuation wires or cables 404, 406 may be wound about cam 400 such that when cable 404 is pulled, cam 400 is urged to rotate about rotational pivot 402 in the direction of arrow 408. Actuation cables 404, 406 may be manipulated from their proximal ends by the user. As cam 400 is rotated in direction 408, a portion of anvil 394 may be engaged by cam 400 thereby forcing stapler cartridge 392 to pivot into an open configuration, as shown in FIG. 20B, when cam 400 is fully rotated, as in FIG. 21 B. Cam 400 may be made into other shapes, *e.g.*, oval, elliptical, *etc.*, depending upon the desired design characteristics. One cam 400 may be utilized, as shown; however, an additional cam may also be affixed on the opposite side of stapler cartridge 392 such that dual cams are configured to open and close simultaneously in parallel. Alternatively, in the same device, the location of stapler cartridge 392 and anvil 394 may be reversed (*e.g.* anvil 394 may be configured to move

toward cartridge 392) depending on the location of the desired target and clearance desired.

Detail views of the stapler assembly is shown in FIGS. 22A to 22D. FIGS. 22A to 22C show cross-sectional side, front, and top views, respectively, of stapler assembly 410.

5 Cartridge housing 412 generally houses a plurality of staples 414 which may be aligned adjacently to one another in one or more rows. The distal ends of both cartridge housing 412 and anvil 422 may be configured to be atraumatic, *e.g.*, blunted, rounded, *etc.*, to the tissue to be affixed. Moreover, cartridge housing 412 and anvil 422 may be configured such that their cross-sectional shape is keyed to the main lumen of the folder assembly so
10 that the orientation of the cartridge housing 412 is maintained relative to the folder assembly, as described above.

FIG. 22C shows a top view of cartridge housing 412 wherein four rows of staples 414 may be aligned. Other variations of cartridge housing 412 may utilize fewer or greater than four rows of staples 414. To deploy staples 414 from cartridge housing 412, two
15 wedges 416, 416', which may be offset or staggered from one another, may each be pulled proximally through cartridge housing 412 via staple actuation wire 420. Wedges 416, 416' may be adjacently positioned to one another but are preferably staggered such that the staples are deployed in a sequenced deployment order. Staple actuation wire 420 may be manipulated via its proximal end by the user when staples 414 are to be deployed out of
20 cartridge housing 412 into the tissue.

Staples 414 may be deployed through staple apertures 418 defined over the surface of cartridge housing 412 in apposition to staple closure surface 424 of anvil 422. As the staggered wedges 416, 416' are pulled proximally, each wedge 416, 416' may engage one or more rows of staples and urge them through staple apertures 418, as shown in FIG. 22A,
25 and through the tissue until they are engaged in corresponding staple detents 426, as shown in FIG. 22D. As further shown in FIG. 22D, which shows a top view of staple closure surface 424 of anvil 422, each staple detent 426 preferably corresponds to the distal ends of each staple 414.

As described above, cartridge housing 412 and/or anvil 422 may be configured to
30 be atraumatic, *e.g.*, blunted, rounded, *etc.*; however, it may be desirable to serrate or otherwise roughen the outside edges of both or either the cartridge 412 and/or anvil 422 to ensure full tissue capture upon clamping of the two surfaces. A variation of the stapler assembly 410 is shown in FIG. 22E, which shows serrations 428 defined along the lengths of cartridge 412 and anvil 422. Serrations 428 may be optionally defined along only one

of cartridge 412 or anvil 422 and it may also be defined only partially along the length. Alternatively, other projections or protrusions, such as spears, may be utilized. In yet another alternative, rather than utilizing projections or serrations 428, the surfaces of cartridge 412 and/or anvil 422 in contact with the tissue may simply be roughened or 5 sharpened to facilitate serrating or roughening the contacted tissue or may employ absorptive materials in the form of pads, coatings or covers to facilitate traction. Such pads, covers or coatings may be formed of cotton, Goretex®, polyester, Velcro, etc., and may remain on the surface of the cartridge once staples are delivery, or alternatively may be transmitted with the staples to remain with the tissue affixed thereby.

10 To facilitate the deployment of the staples 414 as wedges 416, 416' are urged through cartridge housing 412, staple pushers 430 may be utilized. As shown in FIG. 23A, which is a top view of one variation of staple pushers 430 positioned over corresponding staples 414, a single staple pusher 430 may be configured to engage two staples 414 in adjacent rows. When a wedge contacts a staple pusher 430, two adjacent staples 414 may 15 be fired sequentially. FIG. 23B shows a detailed perspective view of one example of a staple pusher 430. In this variation, staple pusher 430 may be comprised of one or more sloped cam surfaces 432, 434 for slidingly engaging a wedge. As a wedge engages a cam surface, it may push staple pusher 430 down towards staples 414 as pusher 430 is guided via one or more guides 436, 438. Staple pusher 430 may then engage a first staple via 20 staple engagement surface 440 and a second staple via staple engagement surface 442. An example of a wedge 446 which may be configured to slide within cartridge housing 412 is shown in the perspective view of wedge platform 444 in FIG. 23C. Although a single wedge 446 is shown in the figure extending from platform 444, two offset wedges may be configured into a single platform or two individual wedges may be utilized adjacent and 25 offset to one another.

As mentioned above, cartridge housing 412 may be manipulated into an open and closed position for clamping over the tissue. To control the closure of cartridge housing 412 against anvil 422, a stapler control handle may be used, as shown in the cross-sectional views of the stapler control in FIGS. 24A and 24B. FIG. 24A shows stapler 30 handle housing 450 which may house the tensioning and releasing mechanism for opening and closing cartridge housing 412 relative to anvil 422. Grip 452 may be provided for the user to grasp while manipulating the device during insertion and deployment as well as to help articulate actuation handle 454 for opening and/or closing cartridge housing 412. Actuation handle 454 may be pivotally connected to housing 450 via pivot 458 and to

actuation linkage 464 via handle pivot 460. When actuation handle 454 is pulled towards grip 452, handle 44 may rotate about pivot 458 and urge actuation linkage 464 to rotate about handle pivot 460. The opposite end of actuation linkage 464 may be rotatably connected via pivot 462 to a translating slide block 466 contained within housing 450.

- 5 Alternatively, it may be desirable to configure the fixation assembly with the staple jaws preferentially biased in an open position by placing tension on actuation cable 404 with a spring placed in device handle (not shown). Upon insertion of the staple jaws into the main lumen, the jaws may be retained in a closed position by the inner diameter of the main lumen. Upon reaching the yoke portion, the jaws would be adapted to bias open into
10 clearance slots 254 (252) to slide onto either side of presented tissue. Once the fixation has occurred, the jaws of the fixation assembly may be directed to a closed position by the yoke, and then the device main lumen as the fixation assembly is withdrawn from the patient.

Slide block 466 may anchor actuation cable 404 thereto via a mechanical anchor
15 470, *e.g.*, crimps, clamps, adhesives, *etc.* An upper surface of slide block 466 may comprise rack 468 having a plurality of gear teeth defined thereon. When actuation handle 454 is pulled and actuation linkage 464 is urged proximally, slide block 466 may be forced proximally within travel guide 480, as indicated by arrow 488, to thereby pull actuation cable 404 proximally and thereby force cam 400 to rotate and open the cartridge housing.
20 Simultaneously, while slide block 466 is translated proximally, rack 468 may engage and urge gear 484 to rotate clockwise in the figure, which in turn may force gear 484 to engage and urge rack 474, which is located on a lower surface of complementary slide block 472, to translate distally within travel guide 478, as indicated by arrow 486.

Complementary slide block 472 may anchor actuation cable 406 thereto via anchor
25 476 in the same or similar manner as anchor 470. Actuation cable 406 may be attached to anchor 476 with a retention spring 482 optionally interposed between anchor 476 and slide block 472 to take up any excess slack in the cable 406. FIG. 24B shows the handle assembly after actuation handle 454 has been actuated and slide blocks 466, 472 have been translated within their respective channels 480, 478 to fully or partially clamp cartridge
30 housing 412 against anvil 422 over the tissue. Once cartridge housing 412 has been clamped over the folded tissue, staple deployment actuator 494 may be rotated or urged to pull staple actuation wires 420 to fire the staples into the tissue. Once staple deployment has been completed, actuation handle 454 may be urged distally to reverse the process

described above to open the clamp for removal from the tissue region or for repositioning the staple assembly in another region of the tissue.

The actuation cables 404, 406 as well as staple actuation wires 420 may each be routed through flexible shaft 456, which connects handle 450 to stapler assembly 410.

- 5 Flexible shaft 456 may be comprised of a tubular member having an outer sheath and an optional inner sheath, either or both of which may be made from any of the polymeric materials described above. The shaft 456 may further utilize braided materials, *e.g.*, superelastic materials such as Nickel-Titanium alloy, integrated throughout to increase column strength and to prevent kinking. Alternatively, shaft 456 may be formed of wire 10 (round or square flat configuration) to enhance compressive and/or tensile strength.

In a further variation, although the tissue approximation device 500 may be configured to be flexible, it may also be desirable to actively or passively curve working body 502 to assist in overall placement of the system within the target organ for optimal presentation of tissue overlap 100 prior to placement of the stapler assembly, as shown in

- 15 the perspective views of FIGS. 25A and 25B. For passive actuation, a curved stylet (not shown) may be placed alongside the actuation rods in the actuation rod channels, or in another available space within the working body 502, to bias the main body 502 in the curvature provided by the stylet. Working body 502 may be optionally configured to have a bending region 504 located proximally of the pod assembly 512. This optional bending 20 region 504 may be configured to facilitate bending of a portion of the working body 502 in any number of directions or only in a specified direction, depending upon the desired results.

In addition, as depicted in the detail view of FIG. 25C, a distal position control 507 may be adapted to fit onto working body 502 via a connector tube 514. Distal position 25 control 507 may be further adapted to be integrated into handle 34 (as shown in FIG. 1).

- Distal position control 507 may comprise a base 506, a lever 508 configured to rotate about pivot 510 located on base 506, a linkage mechanism 516, an adjustment assembly 518, and a curvature linkage 519. An optional cap or seal 517 may be placed over a proximal end of the base 506 to seal or cover an opening to the main lumen of the working 30 body. In operation, lever 508 may be pivotally mounted to base 506 via linkage mechanism 516. Depending on the amount of curvature desired in bending region 504, adjustment assembly 518 can be adjusted, *e.g.*, by rotating the mechanism to adjust tension curvature linkage 519 prior to actuation of lever 508. FIG. 25A depicts the assembly 500 in the non-deployed, *i.e.*, a straightened position of working body 502, while FIG. 25B

depicts full actuation of lever 508 to impart a curvature to the distal end of working body 28. The curvature of bending region 504 may accordingly be adjusted to any intermediate position depending upon the degree of actuation of lever 508. Furthermore, although the degree of bending of the distal portion of the assembly 500 relative to a longitudinal axis 5 of working body 502 is shown to be about 45° in this example, other variations may be adjusted to have a maximum bend of a lesser or greater degree depending upon the desired bending. Moreover, other variations may allow for bending of the assembly 500 in either a unidirectional manner or in any other direction, again depending upon the desired results. It is further contemplated that the bending region 504 may occur at a variety of locations 10 along the shaft of working body 502, such as in the distal or proximal region of the working body or at any point therebetween.

As mentioned above, optional cap or seal 517 may be placed over a proximal end of the base 506 to seal or cover an opening to the main lumen of the working body. FIGS. 25D and 25E show perspective and end views, respectively, of a variation of end cap or 15 seal 517 which may be used to cap the handle of FIG. 25C. End cap 517 may seal the main lumen yet allow passage of devices through the membrane through a small expandable opening 523 covering the main lumen. An optional tab or handle 521 may extend from the cap or seal 517 to facilitate handling of the cover. The cap or seal 517 may be formed from any of the polymeric materials described herein, *e.g.*, silicone.

FIG. 26 shows a variation 520 of how the tissue approximation assembly may be utilized with other devices such as an endoscope 522. In this example, clearance slots (open region 240) may function to provide clearance for an endoscope 522, or other tool, that can be inserted into and advanced through the main lumen 40 of working body 28. During tissue approximation, endoscope 522 may be advanced distally out of main lumen 25 40 and advanced past pod assembly 16. A bending region 524 of endoscope 522 may then be retroflexed to view the results or progress of the tissue approximation and/or fixation using an imaging system 526, *e.g.*, optical fibers, CCD or CMOS imaging system, *etc.*, positioned within a distal end of the endoscope 522.

FIG. 27 shows a portion of flexible shaft 456 of the fixation assembly inserted 30 through main lumen 40 of handle 110 in assembly 490. Handle 110 is partially shown for clarity. As mentioned above, one or several insertion indicators 492 may be defined along a portion of flexible shaft 456 at predetermined positions. These indicators are preferably located near a proximal end of shaft 456 to indicate information to the user. For instance, when shaft 456 is aligned against handle 110 at one particular indicator, this may notify

the user when it is safe for stapler assembly 410 to be opened in a patient body, *e.g.*, when cartridge housing 412 is positioned proximally of the tissue between the yoke members. A second indicator defined along shaft 456 may indicate to the user when the second indicator is aligned against handle 110 that it is safe to clamp stapler assembly 410 over the tissue, *e.g.*, when stapler assembly 410 is positioned fully over the approximated and folded tissue thereby indicating that the cartridge housing 412 may be clamped against anvil 422 and the tissue for staple deployment. Additional indicators may be defined along shaft 456 to indicate various other information, *e.g.*, positional information such as how deep stapler assembly has been inserted relative to the folder assembly. These examples are merely intended to be illustrative and are not limiting in how indicators defined along the shaft 456 may be utilized.

Once the tissue has been affixed, stapler assembly 410 may be removed from the main lumen of the folder assembly and an endoscopic device may be optionally inserted within the main lumen. The endoscopic device may be outfitted with a visual imaging system, *e.g.*, fiberoptic, CCD, CMOS, *etc.*, to view the tissue region. If necessary, stapler assembly 410, or some other tool, may be subsequently inserted through the main lumen to perform additional aspects of the procedure, or to complete the procedure with the placement of additional fixation elements.

In describing the system and its components, certain terms have been used for understanding, brevity, and clarity. They are primarily used for descriptive purposes and are intended to be used broadly and construed in the same manner. Having now described the invention and its method of use, it should be appreciated that reasonable mechanical and operational equivalents would be apparent to those skilled in this art. Those variations are considered to be within the equivalence of the claims appended to the specification.

25 ADDITIONAL DEVICES AND METHODS

Another embodiment of a system for tissue approximation and fixation will now be described that includes a vacuum pod integrated with a fixation assembly. The fixation assembly of this embodiment is similar to the fixation assembly 14 described above. Referring to FIG. 28, a fixation assembly or endoscopic stapler 550 includes a stapler assembly 552 or cartridge assembly connected via a flexible shaft 554 or elongated body having a proximal end and a distal end to a stapler handle 556. The stapler assembly includes a fixation member having a staple cartridge 558, within which one or more staples are housed, and an anvil 560 in apposition to staple cartridge used to provide a staple closure surface when tissue to be affixed is adequately positioned between staple cartridge

and anvil. An optional smooth rubber tip 562 with a guide wire channel 564 may be attached to the distal end of the staple cartridge. The atraumatic tip 562 prevents injury to tissue when the device is advanced down the esophagus, and the guide wire channel allows the fixation assembly to track down a guide wire. The stapler assembly also includes an acquisition member for acquiring tissue. In one embodiment a vacuum pod 566 is attached or integrated into the staple cartridge 558, and a vacuum line or tubing (not shown) extends from the vacuum pod, along the shaft 554 and to the handle 556. It is preferred that the overall insertion diameter of the stapler assembly and flexible shaft plus endoscope is equal to or less than 54 Fr.

With stapler assembly 552 connected at the distal end of flexible shaft 554, the handle 556 is connected at the proximal end of shaft. The flexible shaft 554 is configured to be curved, and in one embodiment can achieve a 4 inch bend radius with a low application of force. The handle 556 may include a housing and grip 572 in apposition to an actuation handle 574. In use, the handle 556 allows the surgeon or user to hold and manipulate the fixation assembly 550 with grip 562 while articulating stapler assembly 552 between an open and close configuration via the actuation handle 574. A lever or staple deployment actuator 570 is also disposed on the handle 556 and is used to deploy staples from the stapler assembly 552. Moreover, the configuration of the handle 556 allows the surgeon or user to articulate the stapler assembly 552.

In one embodiment, the anvil 558 may be pivotally connected via a pivot 578 to the end of flexible shaft 554 as shown in FIG. 30. The staple cartridge 558 may be configured to remain stationary relative to the flexible shaft 554 while anvil 560 may be manipulated into an open and closed configuration with respect to flexible shaft and staple cartridge. However, in another embodiment, the staple cartridge may be pivotally connected to the flexible shaft and the anvil remains stationary. In yet another embodiment, both the anvil and the staple cartridge can pivot into an open and closed configuration relative to the flexible shaft. FIG. 30 also shows one embodiment of the fixation assembly having teeth 579 disposed on the surface of the staple cartridge 558 to better grip the acquired tissue. To manipulate the anvil 560 to an open and closed configuration, a circular or disk-shaped cam 580 may be pivotally attached about rotational pivot 582 located on the side of the proximal end of stapler assembly 552, as best shown in the partial cross-sectional view of FIG. 31. The cam 580 operates in a similar manner to the cam 400, which is described in detail above. Actuation wires or cables 584, 586 may be wound about cam 580 such that when cable 584 is pulled, cam 580 is urged to rotate clock-wise (relative to FIG. 31) about

rotational pivot 582. Actuation cables 584, 586 may be manipulated from their proximal ends by the user. As cam 580 is rotated in a clock-wise direction, a portion of staple cartridge 558 may be engaged by the cam thereby forcing the anvil 560 to pivot into an open configuration, as shown in FIG. 30. One cam may be utilized, as shown; however, an 5 additional cam may also be affixed on the opposite side of stapler assembly 552 such that dual cams are configured to open and close simultaneously in parallel. Alternatively, in the same device, the location of stapler cartridge 558 and anvil 560 may be reversed (e.g. cartridge may be configured to move toward anvil) depending on the location of the desired target and clearance desired.

10 In one embodiment of the fixation assembly 550, there are two rows of staple apertures 588 defined over the surface of the staple cartridge 558, as best shown in FIG. 30. Staples are deployed through the apertures in a similar manner as described in detail above referring to FIGS. 22A to 23C, by pulling a staple actuation wire that in turn moves a wedge in contact with a staple pusher to fire a staple. In this embodiment, the lever or 15 staple deployment actuator 570 is depressed to pull the actuation wire in order to fire the staples from the stapler assembly. Other variations may utilize fewer or greater than two rows of staple apertures. To control the closure of anvil 560 against the staple cartridge 558, the stapler control handle 556 may be used in the same manner as the handle 450 described in FIGS. 24A to 24B. It is noted that in this embodiment of the fixation 20 assembly 550, it is the anvil that is being moved from an open to a closed position relative to the staple cartridge and the flexible shaft.

Generally, when the fixation assembly 550 is advanced over a guide wire through the guide wire channel 564 of the rubber tip and down the esophagus to the stomach cavity, the stapler assembly 552 is preferably in a closed configuration as shown in FIG. 25 29. Further, the fixation assembly may be compatible with the side-by-side insertion of a 8.6 mm diameter flexible endoscope or similar scope. The device will be axially located by referencing external markings on the shaft of the device, or visually by using markings on the head of the stapler assembly 552 relative to the "z-line." In terms of radial location, the device will be rotated and placed while under direct visualization. Once the stapler 30 assembly 552 is in the desired position within the stomach cavity for placing a plication along the stomach wall, the guide wire is removed, and the stapler assembly may be articulated into an open configuration as shown in FIG. 30. A vacuum may then be created at the vacuum pod 566 through a vacuum pod opening 576 to acquire a fold of tissue between the staple cartridge 558 and the anvil 560. It is preferred that a vacuum

device be used to achieve a vacuum level of about 28 inHg to about 29.5 inHg. After the vacuum level has stabilized, the jaws of the stapler assembly 552 are then clamped closed over the tissue and then the staples are deployed into the acquired tissue. Vacuum is then released and the stapler assembly 552 is opened and the device is slightly advanced and 5 rotated to allow for the gastric tissue to pull free from the vacuum pod, or vacuum may be reversed to expel the tissue from the pod. Once the tissue is free, the device is withdrawn and may have the staple cartridge reloaded for another firing if necessary. Multiple plications may be positioned using the fixation assembly 550 anywhere within the stomach cavity or newly created gastric sleeve or pouch.

Another embodiment of a device for tissue acquisition and fixation is shown in FIGS. 32 and 33. FIG. 32 depicts an exploded view of a cross stapler device 600 that is able to place a plication within the stomach wall that is generally perpendicular to the longitudinal body of the stapler device. Stapler device 600 includes a distal frame 602 having a stapler cartridge lumen 604 and a vacuum lumen 606. Near the distal end of the frame 602 is a vacuum opening 608 that is in fluid communication with the vacuum lumen 606. An anvil seat 610 is formed at the distal end of the frame and is in line with, although not in connection with, the staple cartridge lumen 604. A staple cartridge body 612 includes staple pushers 614 at its distal end, cable through holes 616 at its proximal end, and a central hole 618 through the middle of the cartridge body. The staple cartridge body 10 is housed within a cartridge housing 620 having a housing central hole 622 through the middle of the cartridge housing and housing cable through holes 624 that are in line with the through holes 616 of the staple cartridge body. The distal end of the cartridge housing 15 includes an opening (not shown) for the staple pushers 614 to extend through. With the staple cartridge body 612 positioned inside, the cartridge housing 620 is positioned within the staple cartridge lumen 604 of the frame, which also includes a frame central hole 626 that is in-line with the housing central hole 622 and the central hole 618 of the cartridge body. An anvil 628 is secured within the anvil seat 610 with dowel pins 630, however, the anvil may be secured by any other means as well. The anvil is in apposition to the staple pushers 614 and is used to provide a staple closure surface when tissue to be affixed is 20 adequately positioned between staple pushers and anvil. The surfaces of the anvil and the staple pushers each lie in a separate plane that is perpendicular to the longitudinal axis of the device, allowing the cross stapler device to form cross folds or flaps of tissue within the stomach cavity. An optional nose cone 632 may be connected to the distal end of the frame 602, and in one embodiment is partially connected to the anvil seat 610. The nose 25

cone provides an atraumatic tip for the device 600. The stapler cartridge is activated with actuation cables 634, which each include a crimped end or distal end tip 636 that is larger in diameter than the cables. The cables are housed within cable housings 638 and extend from the frame 602 to a proximal end of the cross stapler device 600 to a handle that a user can control. When assembled, the cables 634 are positioned through the housing cable through holes 624 and the cable through holes 616 of the cartridge body 612, and the distal end tips 636 of the cables are secured within a cable block 640. The cable block is positioned within the frame 602 through the frame central hole 628, the housing central hole 622, and the central hole 618 of the staple cartridge body 612. In this embodiment, the cable block 640 directs tension from the cables 634 to the frame 602 while loads are being applied to the clamping and stapling elements, *i.e.*, the cartridge body 612 and staple pushers 614.

In use, the cross stapler device 600 is maneuvered down the esophagus to the stomach cavity. As shown in FIG. 32, an optional scope tube adapter 642 may be connected to the proximal end of the frame 602. The scope tube adapter provides a pathway or a railing for an endoscope to be positioned along the side of the cross stapler device 600 for use during a procedure. Once the cross stapler device is in the desired position within the stomach cavity for placing a transverse or horizontal plication along the stomach wall, the vacuum lumen 606 is connected to a vacuum device for achieving a vacuum at the vacuum opening 608, in order to acquire a fold of tissue between the staple pushers 614 and the anvil 628. The cross stapler device 600 is then activated using the cables 634 to first clamp or compress the acquired tissue by pushing the cartridge housing 620 distally. Mechanisms in the handle of the cross stapler device can be used to push the cables 634 and cable housings 638 distally (towards the anvil), which will in turn push the cartridge housing 620 distally through the frame 602. The cables are being held by the cable block 640 to stabilize the position of the frame and the load carrying ability of the cables, and the central holes 618 and 622 of the cartridge body and housing limit the travel of the cable block and therefore the travel of the cartridge housing as well. With the tissue compressed between the cartridge body 620 and the anvil 628, the cables 634 and cable housings 638 are further pushed distally by mechanisms in the handle to drive the cartridge body 612 and staple pushers 614 distally in order to deploy the staples into the acquired tissue. Either a single or a plurality of staples may be deployed from the staple pushers and into the tissue creating a plication. In another embodiment, only one cable and cable housing may be needed to activate the device 600. Further, it would also be possible to

pull the cables proximally at the handle and then reverse the direction of the load at the distal frame to push the cartridge housing and cartridge body distally by using a pivot bar, gear arrangement, or other such means known in the art.

After stapling the acquired tissue, the vacuum is then released and the cross stapler device 600 is rotated to allow for the gastric tissue to pull free from the vacuum opening 608. Once the tissue is free, the device is withdrawn and may have the staple cartridge reloaded for another firing if necessary. Multiple plications may be positioned using the cross stapler device 600 anywhere within the stomach cavity or newly created pouch, for example a series of plications may be placed one after the other.

Another embodiment of the cross stapler device, designated 600a, is shown in FIG. 34, where like reference numerals are used for designating like elements. This embodiment includes a mechanical device to acquire targeted tissue. In one embodiment, the mechanical device may include a grasper 644 having a grasper cable 646 and claws or pinchers 648 at the distal end of the cable. Instead of using a vacuum to acquire tissue, the grasper is extended with claws opened as shown in FIG. 34, and then the claws are closed to grab and pull tissue between the staple pushers 614 and anvil 618. The frame 602 of this embodiment has been modified to accommodate the grasper. For instance, there is a ramp 650 formed near the distal end of the frame 602 that creates a gap 652 in the anvil. The ramp helps direct the grasper towards the stomach tissue. In this embodiment, the compression and fixation of the acquired tissue are activated in the same manner as described above with reference to the cross stapler device 600.

The fixation assembly or endoscopic stapler 550 is a device intended to facilitate transoral stomach stapling procedures, and can be used as a device for performing a secondary step in a gastric sleeve or pouch formation procedure. For example, the fixation assembly 550 can be used to form one or more plications in the distal end of a formed gastric sleeve to narrow the outlet of the gastric sleeve. The fixation assembly can also be used to reinforce the gastric sleeve, and in some situations close a stoma or fistula created by a gastric sleeve. Use of the fixation assembly of this embodiment as a secondary procedure can occur immediately following the primary procedure, or can be carried out at a later date when, for example, the stomach has remodeled itself due to overeating by the patient or other forces that operate on the plications once they are placed.

The primary gastric sleeves can be created using the fixation assembly 550, or can be created by another device, such as the one disclosed in U.S. Serial No. 10/797,439 ("the '439 application"), titled "Devices And Methods For Placement Of Partitions Within A

Hollow Body Organ." The '439 application is hereby incorporated by reference in its entirety. The tissue acquisition and fixation device disclosed in the '439 application (referred to as "the '439 device") is used to create longitudinal dual fold plications within the stomach wall, by acquiring two folds of tissue and then stapling the folds together.

5 One method of narrowing a distal stoma with the fixation assembly 550 will now be described with reference to cross sectional views shown in FIGS. 35 through 42.

As shown in FIG. 35, the '439 device 660 is placed within the stomach cavity SC with an endoscope 662 positioned along the '439 device to provide visualization of the procedure. The '439 device includes a cartridge member 664 placed longitudinally in

10 apposition to an anvil member 666, and an optional septum 668 is removably positioned between the cartridge member and the anvil member. Vacuum ports 670 can be disposed within the cartridge member 664 and the anvil member 666 to each acquire tissue. Once the '439 device is in position within the stomach cavity, the jaws or the cartridge member and the anvil member are opened as shown in FIG. 35. A vacuum is then created at the

15 vacuum ports 670 to each acquire a separate fold of tissue 672 as shown in FIG. 36. The optional septum helps create the dual folds of tissue. Once the tissue is stabilized within the vacuum ports, the septum 668 is removed as shown in FIG. 37. Referring now to FIG. 38, with the septum removed, the jaws (cartridge member and anvil member) of the '439 device are clamped together and staples are fired out of the cartridge member to secure the

20 dual fold of tissue. After forming the longitudinal plication 676 (see FIG. 43) the '439 device is removed from the stomach cavity leaving the endoscope 662 within the newly formed pouch of tissue as shown in FIG. 39.

As shown in FIG. 40, the fixation assembly 550 is advanced down the esophagus alongside the endoscope 662 so that the stapler assembly 552 is near the distal stoma 678

25 (see FIG. 43) created by the longitudinal plication. Next, the jaws of the fixation assembly are opened, in one embodiment the anvil 560 is rotated away from the staple cartridge 558, and a vacuum is applied to the vacuum pod 566 to acquire tissue. Referring now to FIG. 41, with a fold of tissue 680 positioned between the staple cartridge 558 and the anvil 560, the anvil is clamped down against the staple cartridge, and staples are fired from the staple

30 cartridge to secure the single fold of tissue. The fixation assembly 550 and endoscope 662 are then removed from the stomach cavity, leaving the geometry shown in FIG. 42, which is a cross sectional view taken along line 42-42 of FIG. 43. FIG. 43 is an illustrative view of the stomach cavity showing the longitudinal plication 676 and the single fold of tissue 680 created by the fixation assembly 550 to decrease the diameter of the distal stoma 678.

Additional plications may be placed within or near the pouch at the outlet stoma either circumferentially or longitudinally with respect to the initially placed plication.

In another embodiment, the fixation assembly 550 could also be used to reduce or reinforce multiple orifices defined within the stomach cavity. Multiple plications or fastening lines may be disposed within the stomach cavity to divide the stomach cavity as disclosed in U.S. Serial No. 10/188,547 ("the '547 application"), titled "Method and Device For Use In Tissue Approximation And Fixation." The '547 application is hereby incorporated by reference in its entirety. The plications or fastening lines disclose in the '547 application could be created using the '439 device or the fixation assembly 550.

When placing multiple plications within the stomach cavity, distal stomas 678 formed by the longitudinal plications 676 may need to be narrowed. FIGS. 44 and 45 show the stomach cavity with multiple longitudinal plications 676 and a single fold of tissue 680 formed using the fixation assembly 550 near each of the distal stomas 678 to reduce the size or diameter of the stomas. The procedure will be very similar to the one described above with reference to FIGS. 35 through 43. The fixation assembly 550 can be used to form the single fold of tissue 680 immediately after the plications are created, or the procedure to reduce the distal stomas may occur at any later time. Also, multiple single folds can be created with the fixation assembly around the created pouch or stoma to reduce its diameter even further. As previously stated, the fixation assembly may also be used to reinforce the plications by acquiring the plication and forming a staple line over the previous staple line forming the original longitudinal plication.

Stomas may also be created within the stomach cavity with mechanical devices, such as anchors or bands that are attached to the inner surface of the stomach cavity and then cinched together. For instance, U.S. Serial No. 11/056,327 ("the '327 application"), titled "Method and Devices For Reducing Hollow Organ Volume," discloses attaching anchors or staples to the stomach wall and then cinching them together with a tension member attached to each anchor or staple to form a narrowing of the stomach cavity. Also, U.S. Serial No. 11/067,598 ("the '598 application"), titled "Methods and Devices For Reducing Hollow Organ Volume," discloses attaching intragastric bands to the inner wall of the stomach and then cinching or decreasing the diameter of the band to form a stoma within the stomach cavity. The '327 and '598 applications are hereby incorporated by reference in its entirety.

FIG. 46 shows a stoma 682 created within the stomach cavity SC with an intragastric band 684. After the intragastric band has been secured to the stomach wall and

cinched to form the stoma, the fixation assembly 550 or the cross stapler device 600 may then be advanced to the stomach cavity and positioned to place single folds of tissue 680 around the stoma to decrease the diameter of the stoma. The fixation assembly 550 or the cross stapler device 600 will gather portions of the intragastric band as well as the stomach wall, and therefore, the band will further be secured to the stomach wall. Multiple plications can be formed around the circumference of the intragastric band as desired to reduce the size of the stoma. The fixation assembly or the cross stapler device can be used to reduce a stoma created by any mechanism known in the art that creates stomas within the stomach cavity, such as the cinched anchors disclosed in the '327 application. Also, the fixation assembly or cross stapler device can be used to further secure the mechanical device to the stomach wall.

The fixation assembly 550 can also be used to correct a primary procedure. For example, if a longitudinal plication 676 is placed within the stomach cavity, as discussed above with reference to the '439 device, in a lower position from the gastroesophageal junction ("GEJ") than desired, a proximal stoma 686 may be created as shown in FIG. 47. Usually it is desired that the proximal stoma be completely closed to prevent food from entering there through. In this situation, the fixation assembly 550 may be used to acquire tissue at the proximal stoma 686 and fix the acquired tissue together to close the proximal stoma. FIG. 48 shows the proximal stoma 686 closed by a single fold of tissue 680 that was formed with the fixation assembly 550. In this procedure, the fixation assembly may be reloaded with staples and then used to form a plication or single fold of tissue near the distal stoma to reduce its diameter or overall size.

In another example, the longitudinal plication 676, placed using the '439 device as described above, may be at an angle away from the lesser curve LC of the stomach creating a relatively large distal stoma 676 as shown in FIG. 49. To reduce the size of the distal stoma in this example, the fixation assembly 550 can be used to place multiple plications around the circumference of the distal stoma. FIG. 50A shows a cross-sectional view taken along line 50-50 of FIG. 49, after two single folds of tissue 680 have been created at the distal stoma thereby reducing its diameter. It would also be possible to place more single folds around the stoma depending on the desired diameter. In another embodiment, the larger than desired stoma shown in FIG. 49 may also be reduced by using the '439 device to place a dual fold in the middle of the stoma by acquiring and fixing tissue from the anterior and posterior walls of the stomach. The '439 device could be redeployed to the stomach cavity and positioned at the distal stoma 678 to acquire and fix a

dual fold of tissue 674 within the distal stoma as shown in FIG. 50B. Due to the placement of the dual fold in this embodiment, two smaller outlets 688 are formed at the distal stoma 678.

The cross stapler device 600 is also a device intended to facilitate transoral stomach stapling procedures, and can be used as a device for performing a secondary step in a gastric sleeve formation procedure. For example, the cross stapler device 600 can be used to form one or more cross-folds within a formed gastric sleeve to narrow the outlet of the gastric sleeve, and/or to act like a valve within the gastric sleeve. Use of the cross stapler device as a secondary procedure can occur immediately following the primary procedure, or can be carried out at a later date when, for example, the stomach has remodeled itself due to overeating by the patient or other forces acting on the plications.

As described above, the '439 device can be used to form a longitudinal plication 676 within the stomach cavity SC to create a gastric sleeve or pouch with a distal stoma or outlet 678. Referring now to FIG. 51, after forming the gastric sleeve with the '439 device, or any other device, the cross stapler device 600 can be advanced down the esophagus and positioned within the gastric sleeve at a desired location for forming a cross fold or flap of tissue 690. Once in position, the cross stapler device can acquire tissue from the lesser curve LC of the stomach, either with a vacuum pod or a grasper, depending on the embodiment. After acquiring the tissue between the staple pushers 614 and the anvil 628, the cross stapler device is actuated to secure the cross fold of tissue with a plurality of staples. The cross fold of tissue is a fold of tissue that is generally perpendicular to the longitudinal plication 676, and acts similar to a flap of a valve. A cross-sectional view taken along line 52-52 of FIG. 51 is shown in FIG. 52 with the cross stapler device removed for clarity. It is also contemplated that the cross stapler device can form a cross fold of tissue on the longitudinal plication 676 as well, or on the anterior or posterior wall of the stomach. Further, the cross stapler device can be used to place two cross folds of tissue opposite of each other in the gastric sleeve as shown in FIG. 53 to form a valve-like structure.

In another embodiment, the '439 device could be used to over-staple an existing dual fold of tissue at the distal stoma of a gastric sleeve to reinforce the dual fold. Reinforcing the staple line near the distal stoma may be desired because over time the distal stoma or outlet could begin to stretch out and/or the staples could begin to loosen as well. FIG. 54 depicts an existing longitudinal plication 676 within the stomach cavity, and the '439 device 660 being positioned near the distal stoma to reacquire the dual fold of

tissue and place another staple line over the preexisting staple line. When reacquire the dual fold of tissue, the '439 device will not include the optional septum. It has been contemplated that the '439 device could include only a single vacuum port disposed between the cartridge member and anvil instead of having a vacuum port in each of the 5 cartridge member and anvil. The '439 device with a single vacuum port could more easily reacquire the dual fold of tissue already secured together to form the longitudinal plication.

In one embodiment, a laparoscopically placed band 692 (such as the silastic band used in a VBG procedure) could be positioned around the outer surface of the stomach to form an outlet stoma 694 after a gastric sleeve has been formed within the stomach cavity 10 by placing a longitudinal plication 676 within the stomach cavity as shown in FIG. 55. The longitudinal plication could be placed transorally with the '439 device, and then the band 692 could be placed laparoscopically around the stomach at the distal outlet of the pouch or sleeve created by plication 676. This embodiment reduces the volume of the stomach cavity. Such a band is used in a procedure known in the art as a vertical, banded 15 gastroplasty ("VBG"), and is shown in FIG. 2 of U.S. Patent No. 6,773,440, which is hereby incorporated by reference. Such an externally/ laparoscopically placed band may also be formed of polyester, PTFE, silicone impregnated mesh, silicone or other biocompatible materials that limit erosion and promote tissue in-growth and healing.

Other methods could also be used to further reduce the diameter of a distal stoma 20 of a gastric sleeve. In one embodiment, a fabric/mesh band 696 having a tensioning member that is sutured to the band in a purse-string configuration can be attached to the stomach wall near the distal stoma 678 of the gastric sleeve as shown in FIG. 56. The fabric/mesh band, and other intragastric bands that may be used as well, are disclosed in the '598 application, which has already been incorporated by reference. FIG. 56 shows the 25 longitudinal plication 676 placed within the stomach cavity and the fabric/mesh band attached near the distal stoma 678 and cinched to reduce the diameter of the stomach. The fabric/mesh band may be attached to the stomach wall with sutures, staples, anchors, hooks, rivets, adhesives, or any other means. In one embodiment, the cross stapler device 600 is used to secure the fabric/band to the stomach wall. Further, the cross stapler device 30 could be used to secure other intragastric bands or pledget that are disclosed in the '598 application. In another embodiment, the method of cinching together staples or anchors in the stomach cavity disclosed in the '327 application, which has already been incorporated by reference, could also be used within the gastric sleeve to reduce the diameter of a distal stoma.

In another embodiment, a stent, such as a nitinol stent, could be secured within the gastric sleeve near the distal stoma. The stent would be positioned similar to the fabric/mesh band as shown in FIG. 56. In use, a stent having an expanded diameter that is larger than the diameter of the distal stoma may be chosen, so that the stent will be secured 5 within the gastric sleeve by friction. The stent would provide a surface for tissue to grow around, thereby reducing the diameter of the distal stoma. In another embodiment, a stent may be secured near the distal stoma that is biased to a closed position, so that once secured within the gastric sleeve, the stent will reduce the diameter of the distal stoma. In this last embodiment, the stent may be secured to the gastric sleeve with sutures, staples, 10 anchors, or the like. In yet another embodiment, a valve could be placed near the distal stoma of the gastric sleeve. The valve would block incoming food until the pressure of the built up food would force the valve open. There are several valves disclosed in U.S. Serial No. 11/091,023 ("the '023 application"), titled "Systems And Methods For Treating Obesity," that can be secured within the gastric sleeve. The '023 application is hereby 15 incorporated by reference in its entirety.

Another method for narrowing the distal stoma of a gastric sleeve would be to place a surgical clip at the distal stoma. One example of a surgical clip is disclosed in U.S. Pat. No. 6,641,593 ("the '593 patent"), titled "Tissue Connector Apparatus And Methods," and is hereby incorporated by reference in its entirety. Surgical clips, such as the one 20 described in the '593 patent may be formed of a deformable wire made of a shape memory alloy like nitinol. Once attached near the distal stoma 678 and released, the surgical clip will begin to self close and narrow the stoma as shown in FIG. 57. The surgical clip may be secured near the distal stoma with sutures, staples, anchors, or the like.

In yet another embodiment for reducing the diameter of the distal stoma, a plurality 25 of magnets may be implanted into the tissue around the distal stoma 678 to close the distal stoma until the magnetic force is overcome by gastric pressure due to the presence of food filling the gastric sleeve. In one embodiment, a first magnet 700 may be secured or implanted within the anterior wall of the stomach cavity and a second magnet 702 may be secured or implanted within the posterior wall of the stomach cavity as shown in FIGS. 58 30 and 59. One method of securing the magnets to the stomach wall would be to place them in a closed polyester or PTFE sleeve or enclose them with a coating that is sutured or stapled to the stomach wall. Another method of securing the magnets, would be to form a hole within the lining of the stomach and then position the magnet into the stomach wall. As shown in FIG. 59, the magnets will attract one another to close the distal stoma 678.

As the patient eats and food builds up within the gastric sleeve, the pressure of the built up food will force the magnets apart from one another to allow the food to pass. The magnets will not completely close the distal stoma, and therefore liquids will be allowed to pass through smaller openings 704 at the distal stoma that are not sealed by the magnets.

5 Another embodiment of reducing the diameter near the distal stoma of the gastric sleeve involves delivering energy scarification or ablation using RF, ultrasound, HIFU, microwave, laser or other energy to induce tissue shrinkage or a desired amount of stricture to reduce the distal stoma. Embodiments for using ablation and remodeling tissue are disclosed in U.S. Pat. No. 6,866,663, titled "Method For Treating A Sphincter," which
10 is hereby incorporated by reference. As shown in FIG. 60, a catheter 706 having a distal tip 708 and an energy delivery device 710 has been introduced down the esophagus to the stomach cavity. The energy delivery device has been extended from the distal tip of the catheter and positioned a certain distance within the stomach tissue. In this position, energy, such as those listed above, may be applied through the energy delivery device to
15 the stomach tissue near the distal stoma 678 of the gastric sleeve formed by the longitudinal plication 676. The catheter may be rotated within the gastric sleeve and the energy delivery device repositioned within the stomach cavity as many times as needed until the desired diameter at the distal stoma is achieved. FIG. 61 shows the catheter 706 removed and a reduced diameter near the distal stoma caused by the shrinkage of tissue
20 near the distal stoma. In other embodiments, the catheter could be used to deliver cryogenic energy, caustic agent, or other chemical to cause tissue shrinkage near the distal stoma.

In another embodiment, the diameter of the distal stoma may be reduced by introducing a bulking agent into the nearby tissue. A method of introducing a bulking agent into the stomach tissue is disclosed in U.S. Serial No. 10/386,241 ("the '241 application"), titled "Method For Treating Morbid Obesity," which is hereby incorporated by reference. As shown in FIG. 62, a catheter 712 having a distal tip 714 is introduced down the esophagus to the gastric sleeve formed by the longitudinal plication 676. Once in position an ejection needle 716 is extended from the distal tip of the catheter and into the stomach tissue. A bulking agent is then ejected from the ejection needle and into the stomach tissue. The catheter may be rotated and the ejection needle repositioned within another area of the stomach tissue to eject more of the bulking agent until the desired diameter of the distal stoma is achieved. Preferred bulking agents are any of those solutions disclosed in the '241 application, and include collagen, silicone, and other
30

biocompatible polymers. Additional bulking agents that may be injected into the tissue surrounding the distal stoma or outlet include tissue cells, and injectable embolization devices, such as coils and beads. FIG. 63 shows a bulge of tissue 718 created by injecting a bulking agent into the tissue near the distal stoma 678 to reduce its diameter.

5 In another embodiment, the distal stoma of the gastric sleeve could be reduced by laparoscopic placement of an external single or dual fold of tissue near the distal stoma. A single fold may be placed on the external surface of the stomach using the fixation assembly 550, and a dual fold of tissue may be placed using the '439 device. FIG. 64 shows a cross-sectional view of the stomach cavity taken near the distal stoma, with an
10 external single fold of tissue 720 placed along the lesser curve of the stomach near the outlet of the gastric sleeve. During the procedure, an endoscope could be used to help position the fixation assembly or other stapler device on the external surface of the stomach where the distal stoma is located.

15 Although the above embodiments teach placing a restriction near the distal stoma of the gastric sleeve, by placing additional folds, devices (intragastric band and clips), or by restructuring the stomach tissue (ablation and ejection of bulking agents), these restrictions can be placed anywhere along the gastric sleeve. Further, multiple restrictions can be created or placed along the gastric sleeve in combination to create a labyrinth or series of restrictions.

20 In describing the system and its components, certain terms have been used for understanding, brevity, and clarity. They are primarily used for descriptive purposes and are intended to be used broadly and construed in the same manner. Having now described the invention and its method of use, it should be appreciated that reasonable mechanical and operational equivalents would be apparent to those skilled in this art. Those variations
25 are considered to be within the equivalence of the claims appended to the specification.

WE CLAIM:

1. A tissue fixation device, comprising:

an elongated body having a proximal end and a distal end; and

a fixation assembly connected to the distal end of the elongated body having an

5 acquisition member and a fixation member;

wherein the acquisition member is integrated into a portion of the fixation member.

2. The device of claim 1, wherein the acquisition member defines at least one opening adapted to adhere tissue thereto via a vacuum.

3. The device of claim 2, further comprising at least one vacuum tubing positioned along at least a portion of the elongated body.

4. The device of claim 1, wherein the acquisition member is a vacuum pod permanently attached to at least a portion of the fixation assembly.

5. The device of claim 1, wherein the fixation assembly includes an atraumatic distal tip.

15 6. The device of claim 5, wherein the distal tip defines a guide wire lumen therethrough.

7. The device of claim 1, wherein the elongated body is configured to be curved.

8. The device of claim 1, further comprising a handle connected to the proximal end of the elongated body.

20 9. The device of claim 8, wherein the handle includes at least one actuation mechanism adapted to articulate the fixation assembly from a first configuration to a second configuration.

10. The device of claim 8, wherein the handle is adapted to deploy a plurality of staples from the fixation assembly.

11. The device of claim 1, wherein the fixation assembly comprises a staple cartridge and an anvil in apposition to the staple cartridge.

12. The device of claim 11, wherein the staple cartridge is adapted to rotate about a pivot relative to the anvil from a closed configuration to an open configuration.

30 13. The device of claim 11, wherein the anvil is adapted to rotate about a pivot relative to the staple cartridge from a closed configuration to an open configuration.

14. The device of claim 1, wherein the acquisition member is a mechanical device.

23. The method of claim 18, wherein affixing the acquired tissue, the cartridge assembly fires staples to affix the tissue.

24. The method of claim 18, further comprising releasing the region of tissue from the acquisition member.

5 25. A method of treating tissue within a hollow body organ, comprising:
performing a primary procedure to reduce the volume of the hollow body organ;
and
placing at least one plication to increase the success of the primary procedure.

10 26. The method of claim 25, wherein placing the at least one plication reinforces the primary procedure.

27. The method of claim 25, wherein placing the at least one plication further reduces the volume of the hollow body organ.

15 28. A method of treating tissue within a hollow body organ, comprising:
placing at least one initial plication within the hollow body organ forming at least one reduced orifice having an inlet and an outlet; and
placing at least one secondary plication to reduce the outlet formed by the at least one initial plication.

29. The method of claim 28, wherein placing the at least one secondary plication perpendicular to the at least one initial plication to block the outlet.

20 30. A method of treating tissue within a hollow body organ, comprising:
placing at least one initial plication within the hollow body organ forming at least one reduced orifice having an inlet and an outlet; and
performing at least one secondary procedure to reduce the outlet formed by the at least one initial placation, the secondary procedure being chosen from the group consisting of: placing an additional plication at or near the outlet, injecting a bulking agent at or near the outlet, placing a valve at or near the outlet, placing a stent at or near the outlet, laparoscopically placing an external band at or near the outlet, placing an internal band at or near the outlet, applying energy to the tissue at or near the outlet, and applying a caustic agent or sclerosing agent at or near the outlet.

15. The device of claim 14, wherein the mechanical device is a grasper having a cable and a claw disposed at the distal end of the cable.

16. The device of claim 1, wherein a hinged member pivotally connects the fixation assembly to the distal end of the elongated body.

5 17. A tissue fixation device, comprising:

a flexible shaft having a proximal end and a distal end; and

a cartridge assembly connected to the distal end of the elongated body having an acquisition member and a fixation member, wherein the fixation member includes a first jaw and a second jaw capable of pivoting relative to one another from a closed position to 10 an open position, and the acquisition member includes a vacuum pod fixed to at least one of the first and second jaws;

wherein when the first and second jaws are in the open position, the vacuum pod acquires and holds at least one fold of tissue between the first and second jaws, and the first and second jaws pivot into the closed position to plicate the tissue.

15 18. A method of acquiring and affixing tissue from within a hollow body organ, comprising:

positioning a cartridge assembly attached to a distal end of an elongated body within the hollow body organ adjacent to a region of tissue to be acquired;

20 articulating at least one jaw of the cartridge assembly from a closed configuration to an open configuration;

acquiring the region of tissue with an acquisition member attached to at least a portion of the cartridge assembly, the region of tissue is acquired and held between the at least one jaw of the cartridge assembly; and

25 affixing the acquired tissue by articulating the at least one jaw of the cartridge assembly from the open configuration to the closed configuration.

19. The method of claim 18, further comprising inserting a guide wire into the hollow body organ and advancing the cartridge assembly over the guide wire.

20. The method of claim 18, further comprising employing an imaging device alongside or integral to the elongated body and into the hollow body organ to view the 30 cartridge assembly and the region of tissue to be acquired.

21. The method of claim 18, wherein acquiring the region of tissue with the acquisition member, the acquisition member is a vacuum pod.

22. The method of claim 18, wherein acquiring the region of tissue with the acquisition member, the acquisition member is a mechanical device.

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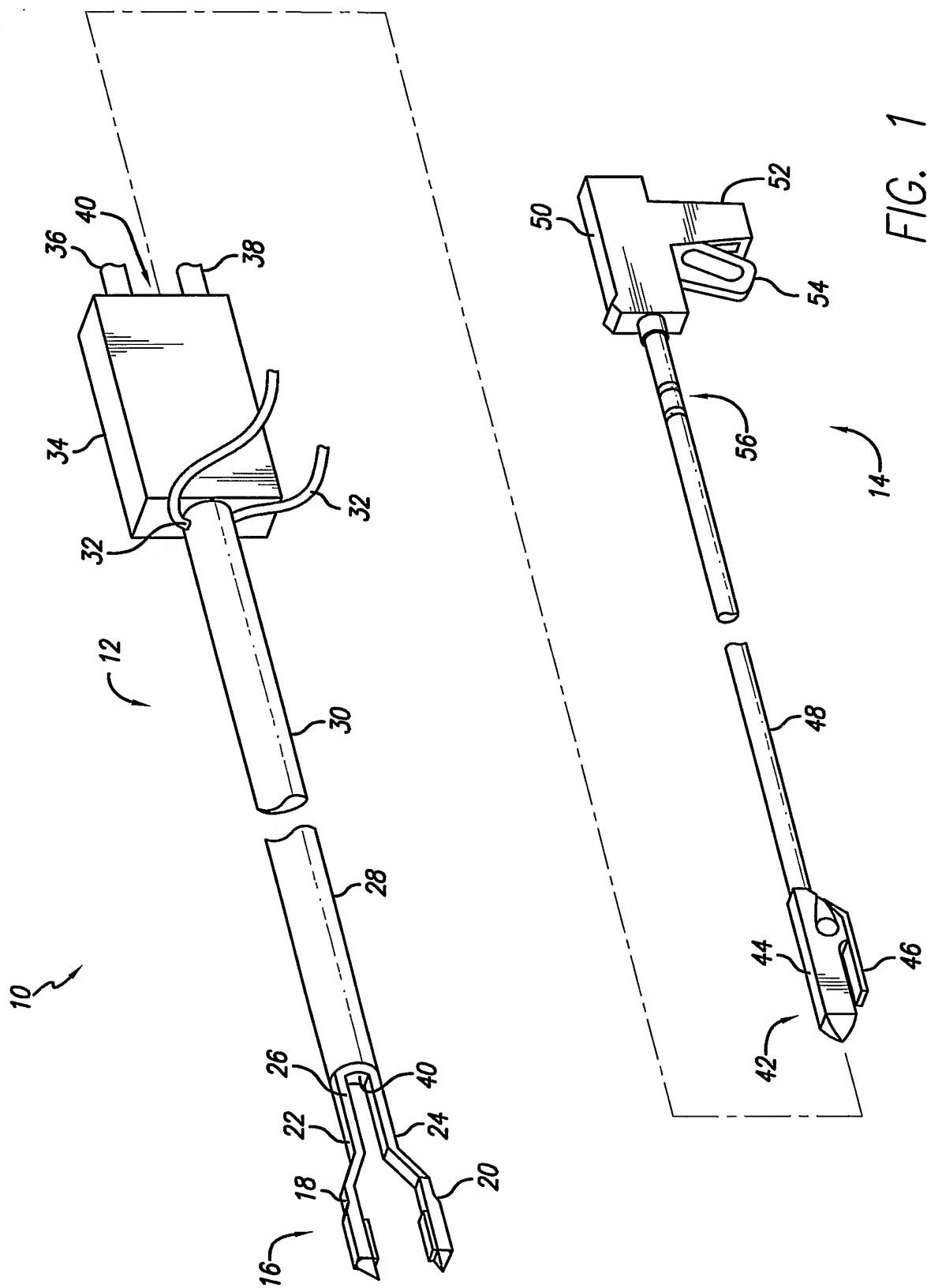


FIG. 1

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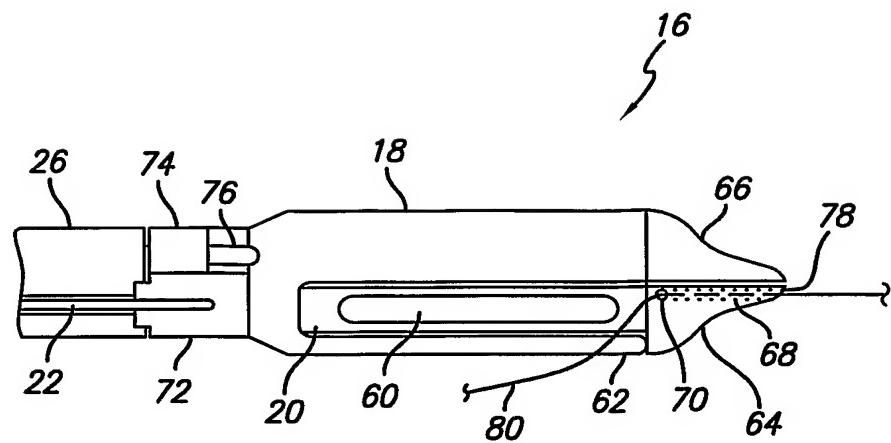


FIG. 2A

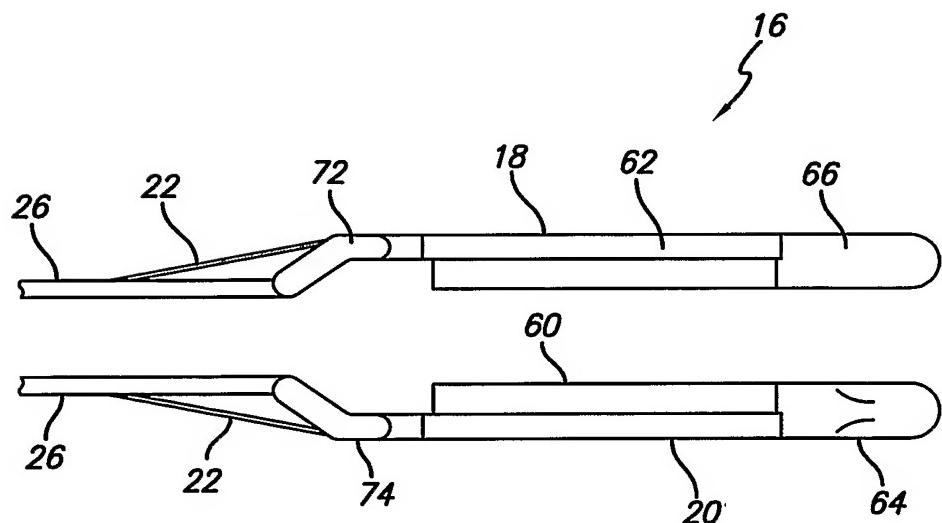


FIG. 2B

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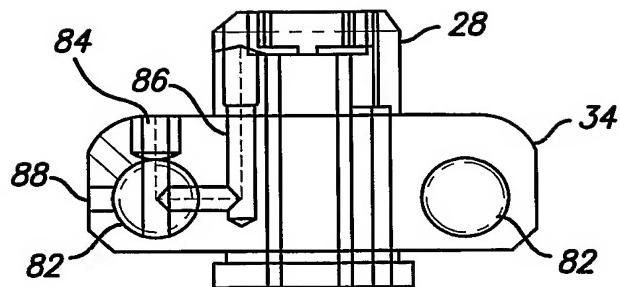


FIG. 2C

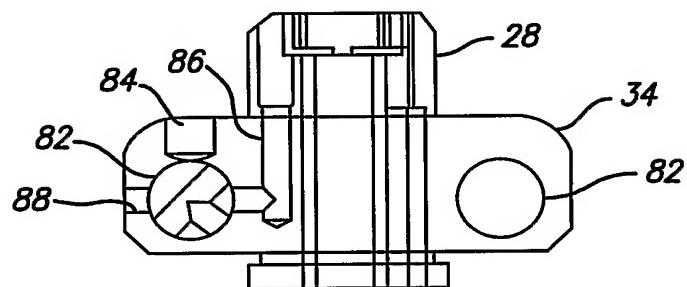


FIG. 2D

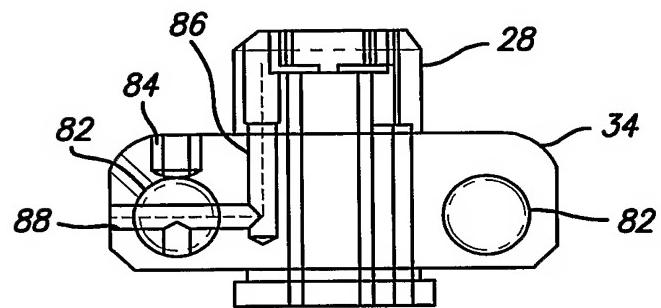


FIG. 2E

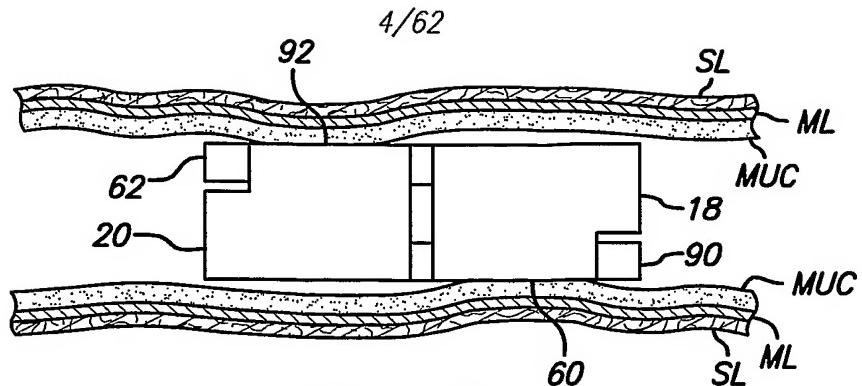


FIG. 3A

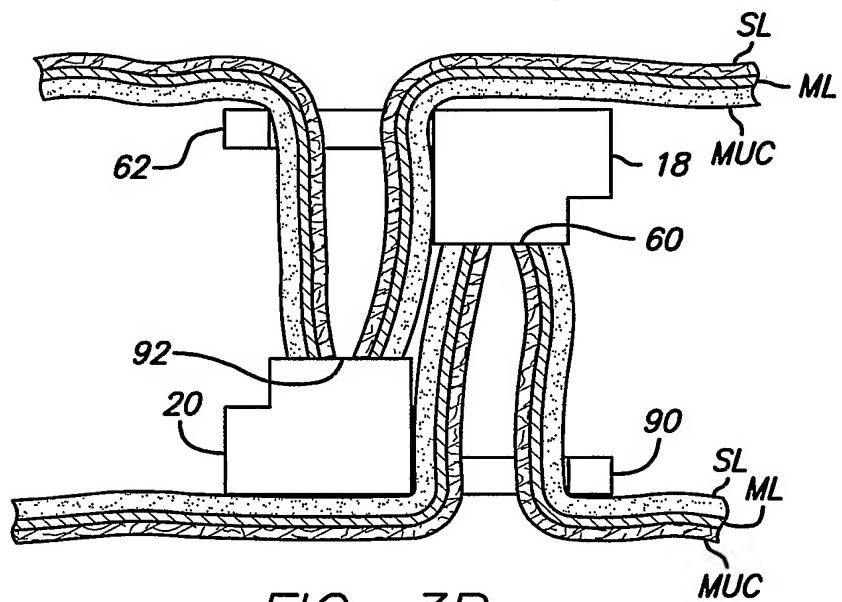


FIG. 3B

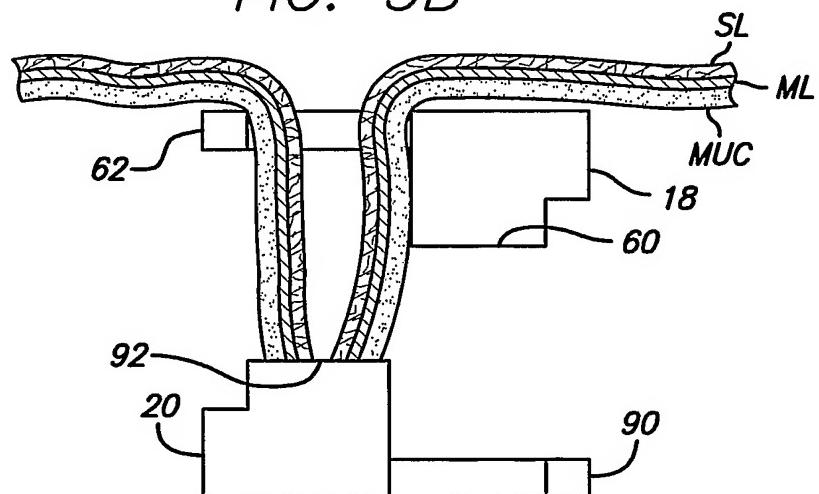


FIG. 3C

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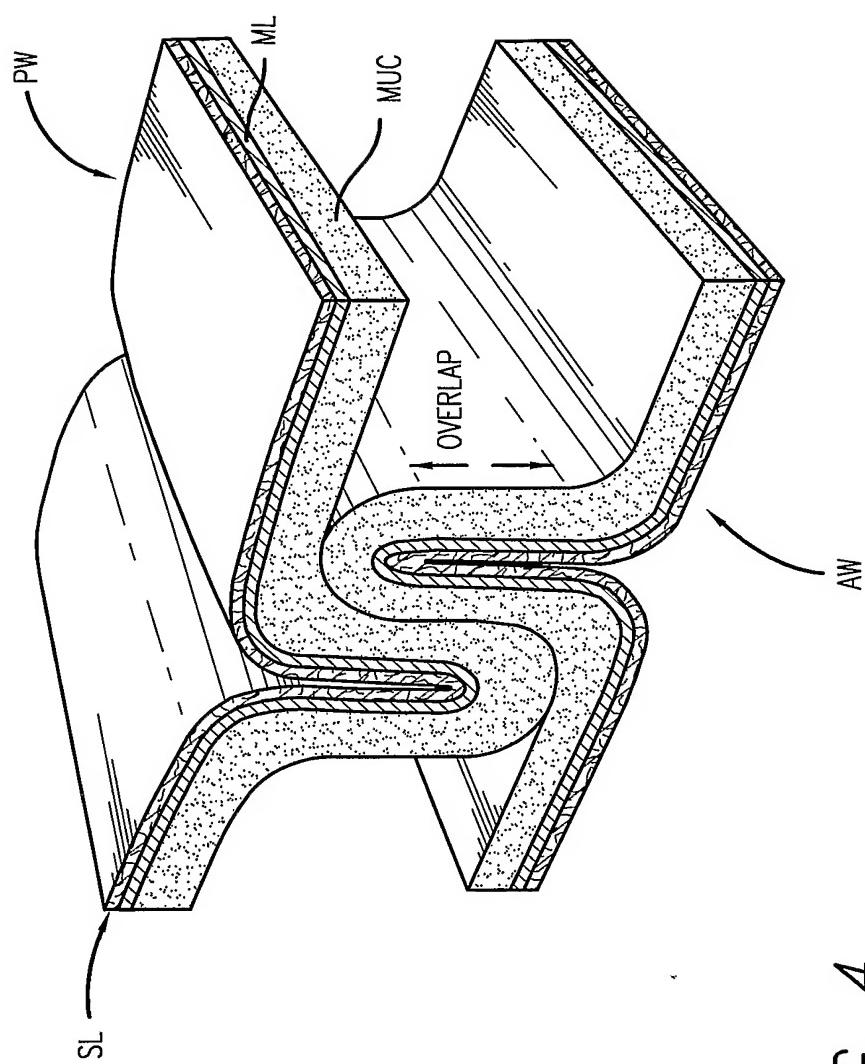


FIG. 4

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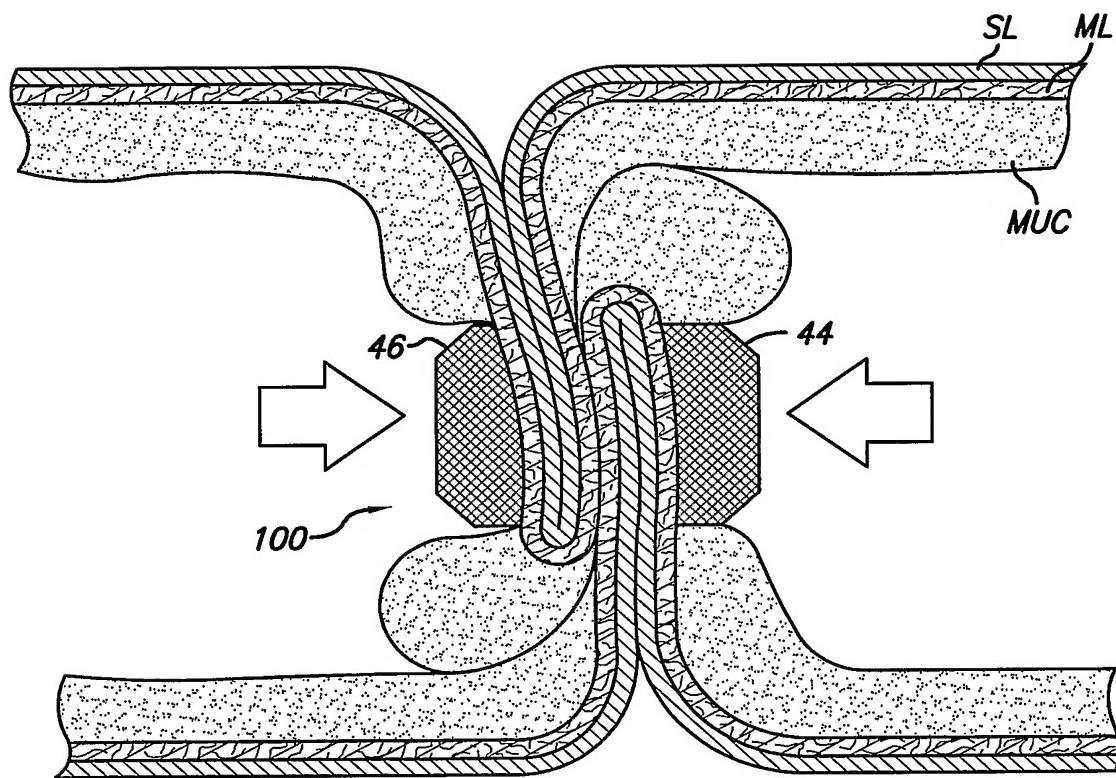


FIG. 5

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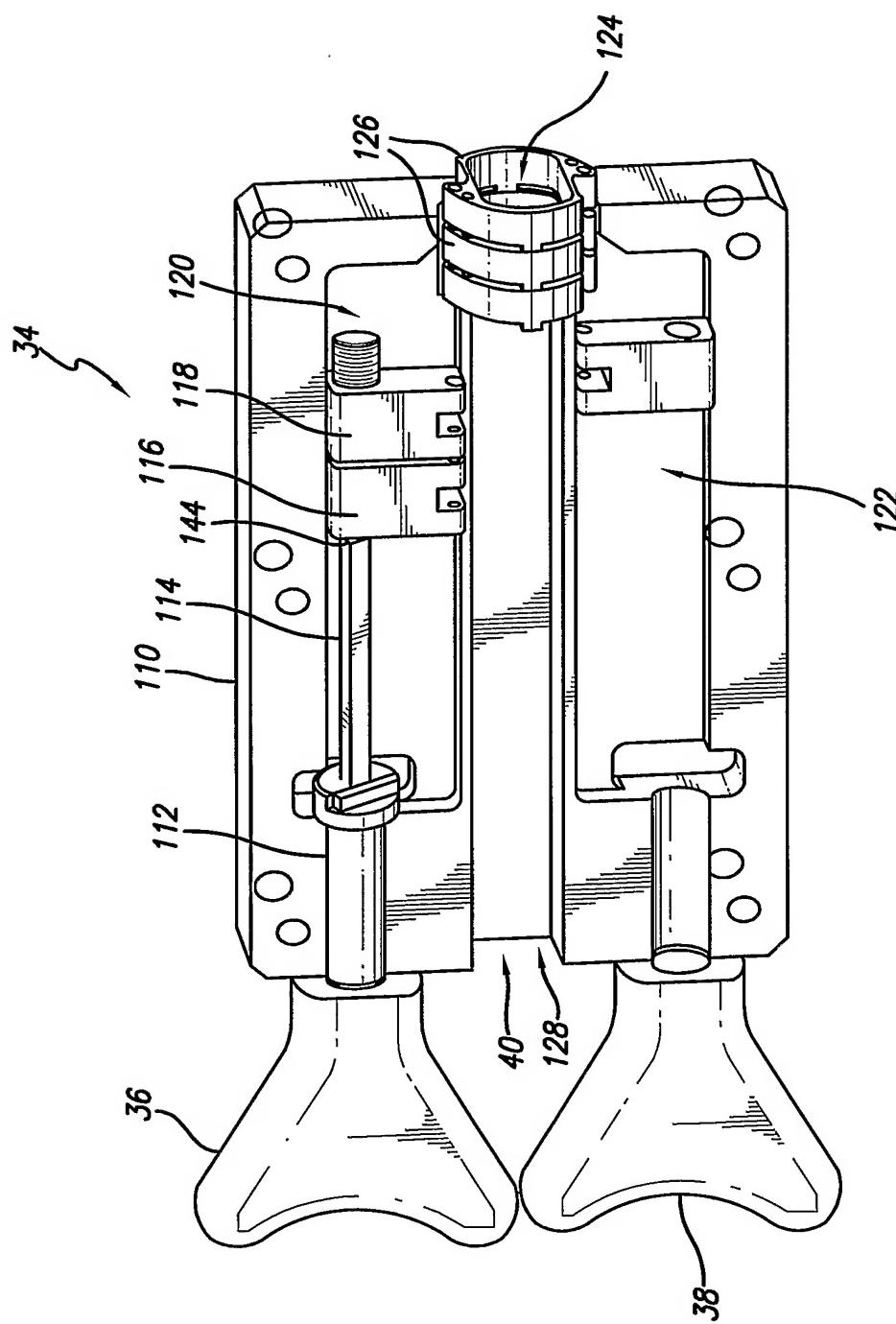


FIG. 6A

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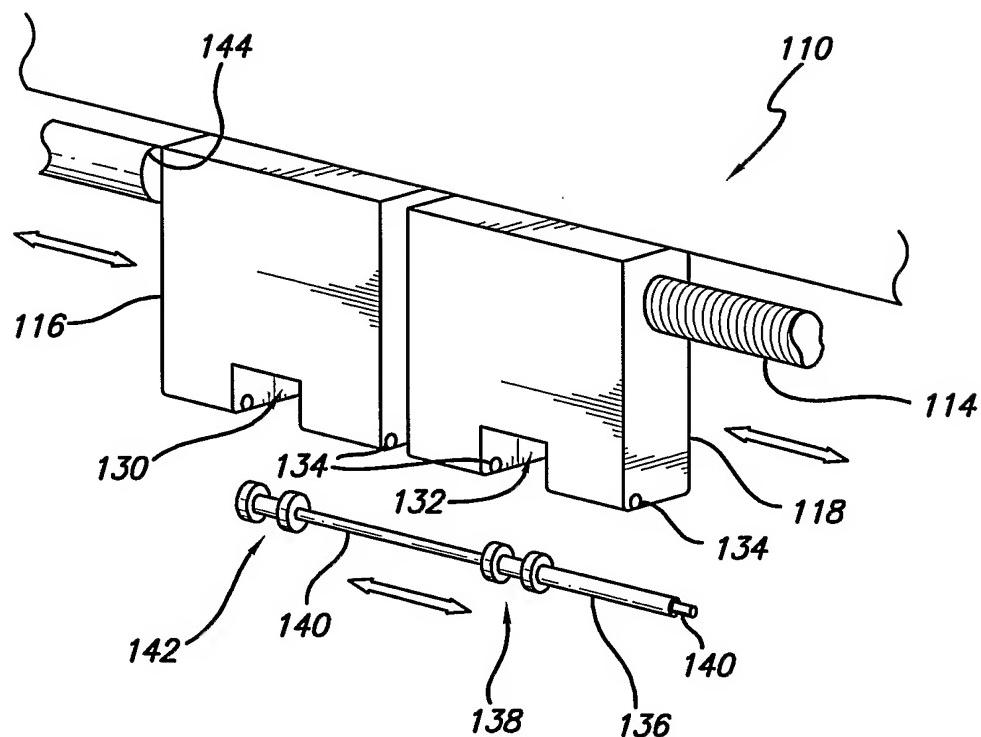


FIG. 6B

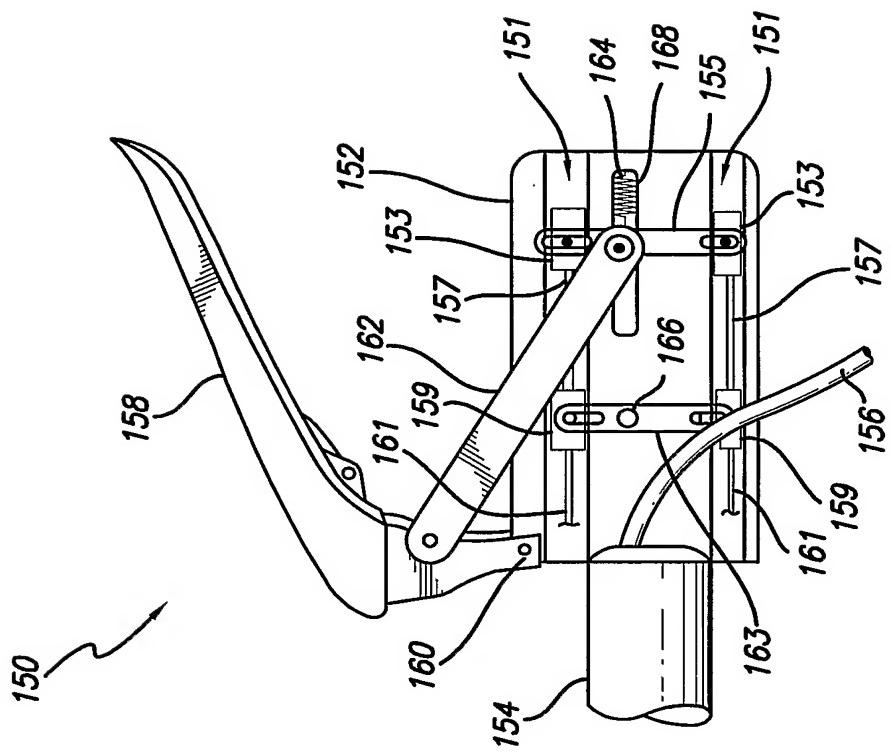


FIG. 7

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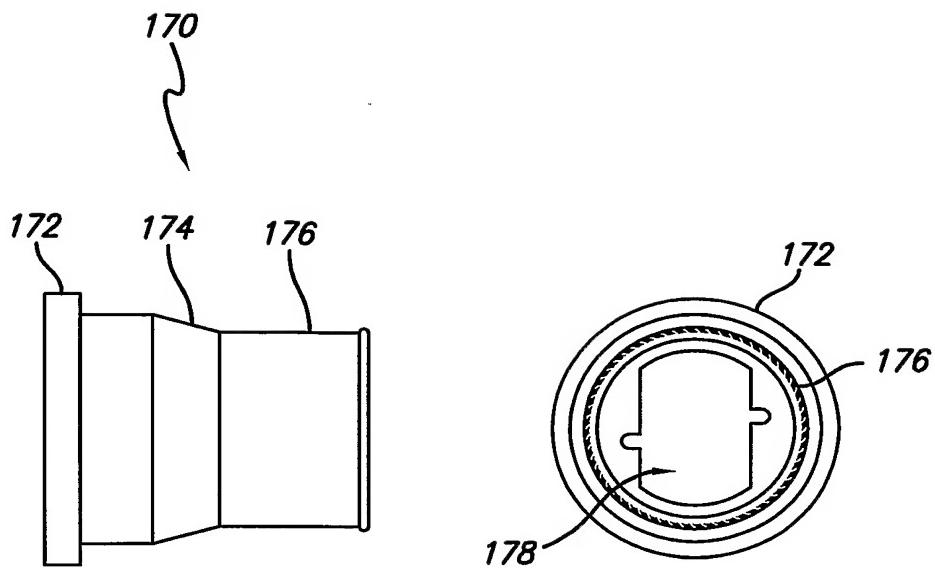


FIG. 8A

FIG. 8B

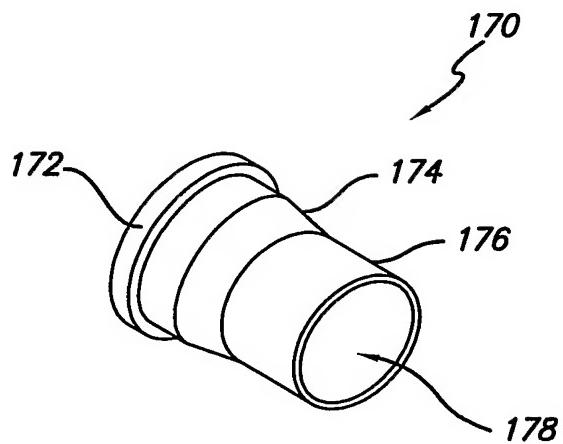


FIG. 8C

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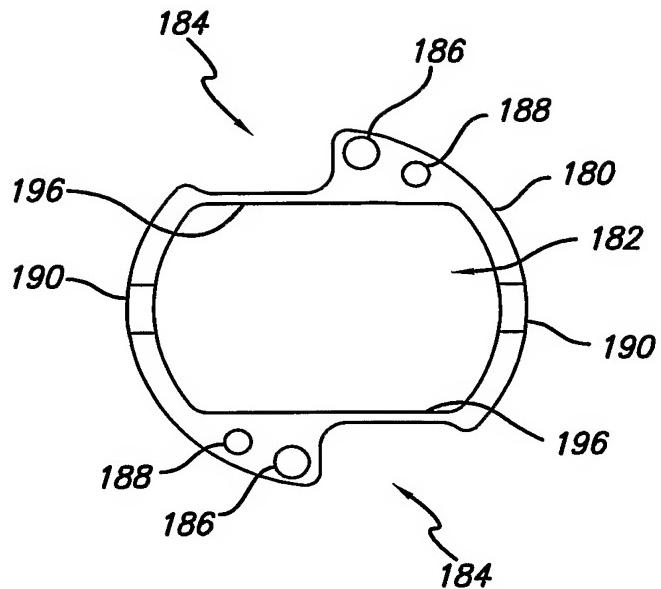


FIG. 9A

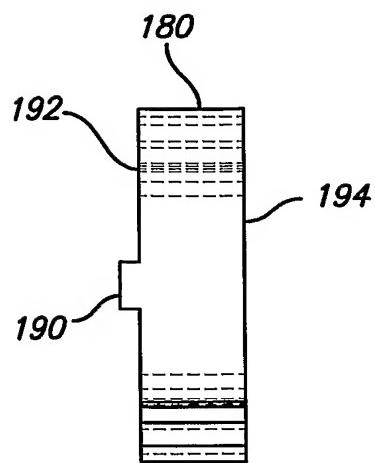


FIG. 9B

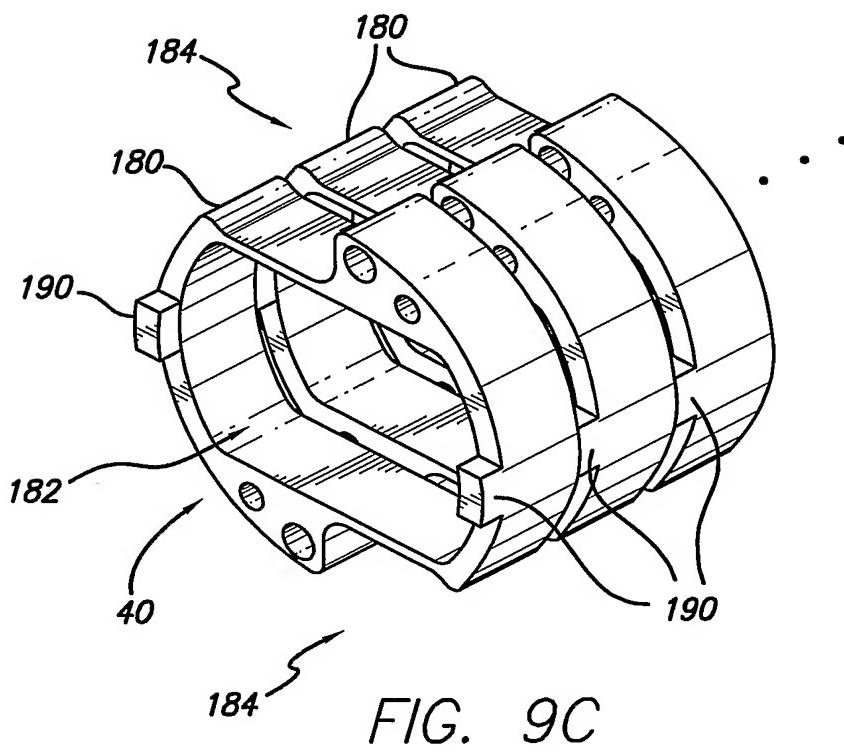


FIG. 9C

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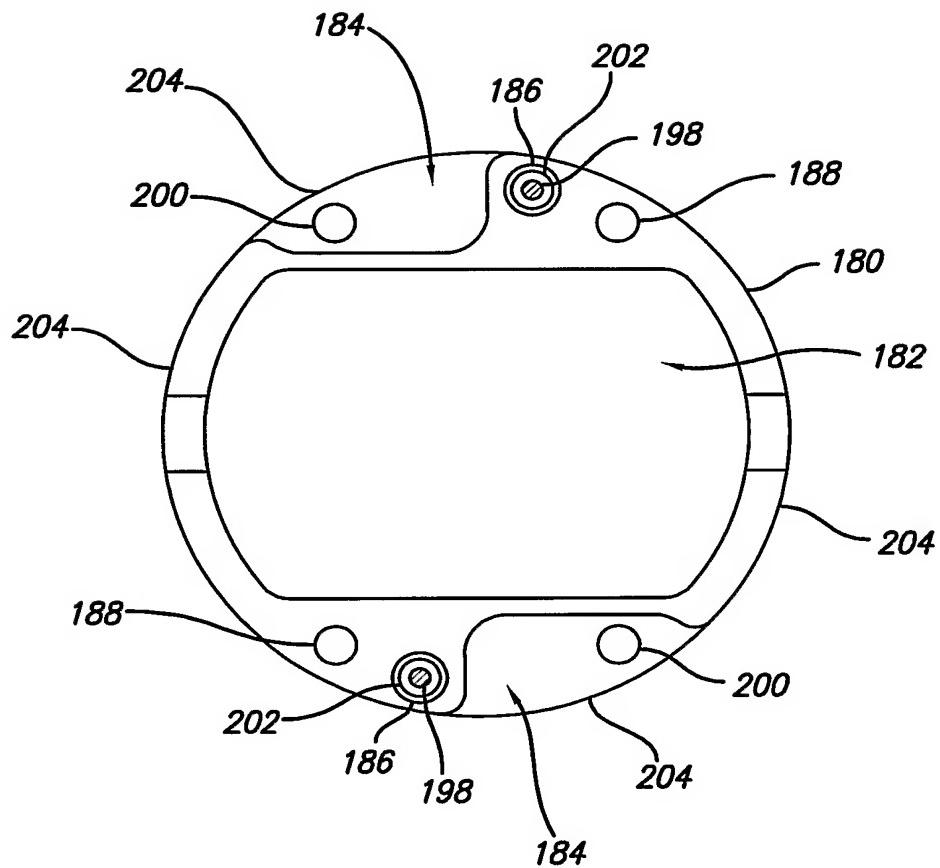


FIG. 9D

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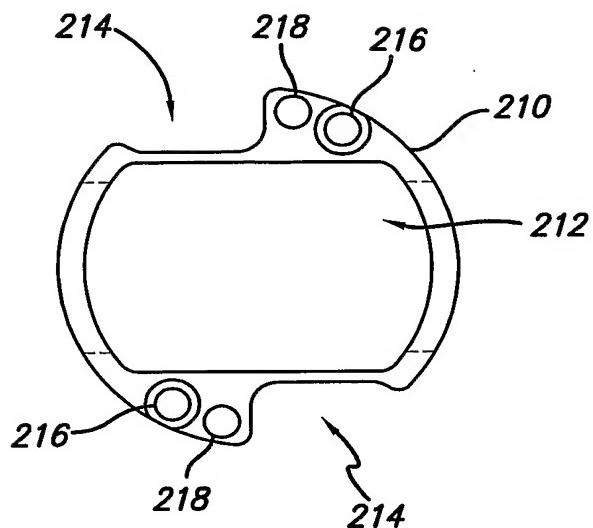


FIG. 10A

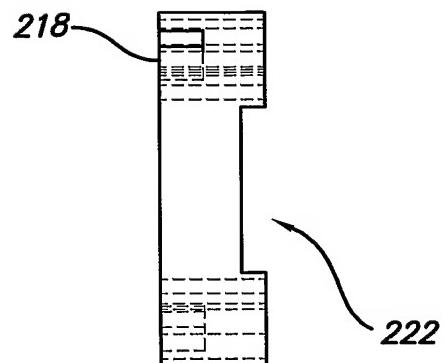


FIG. 10B

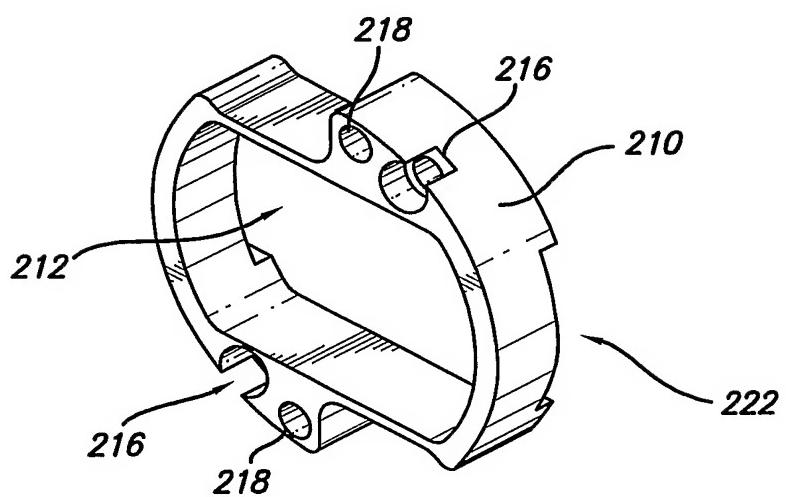


FIG. 10C

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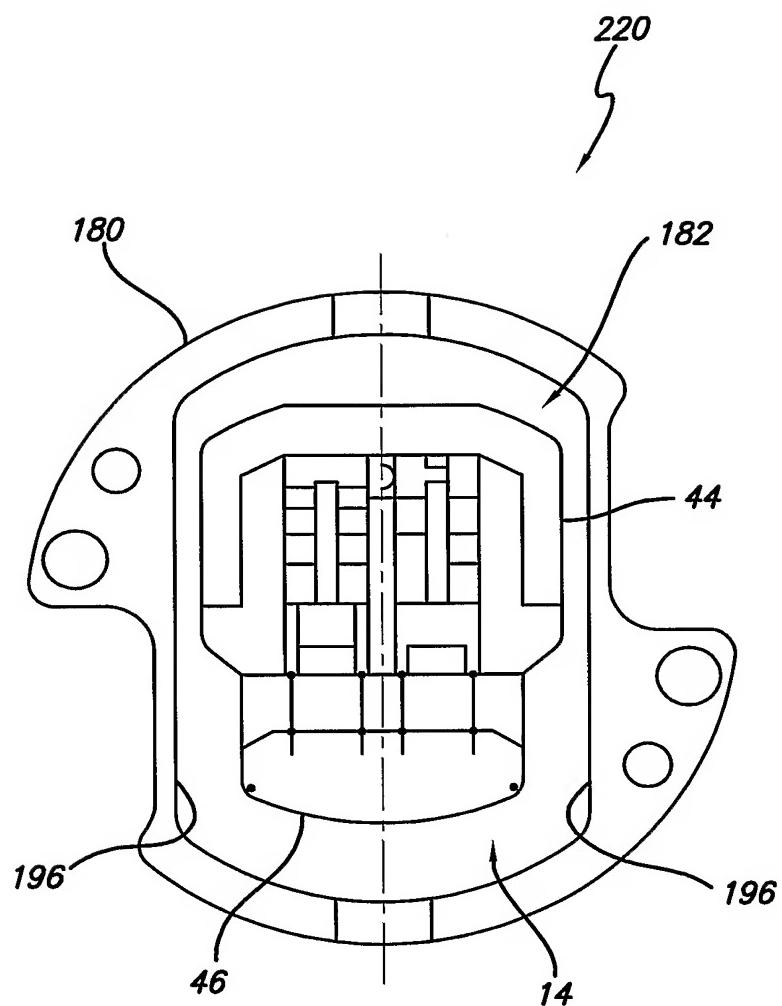


FIG. 11

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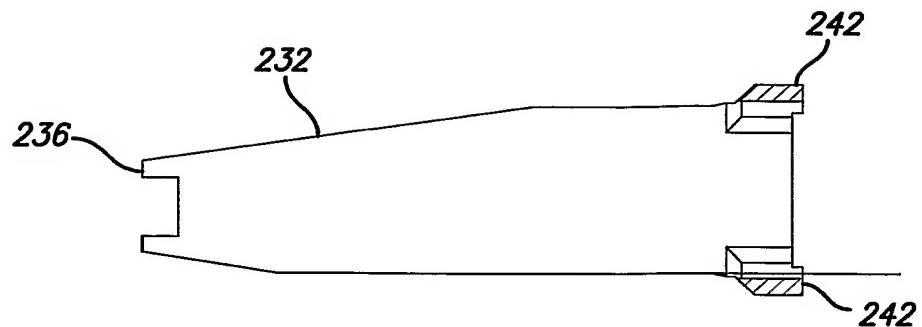


FIG. 12B

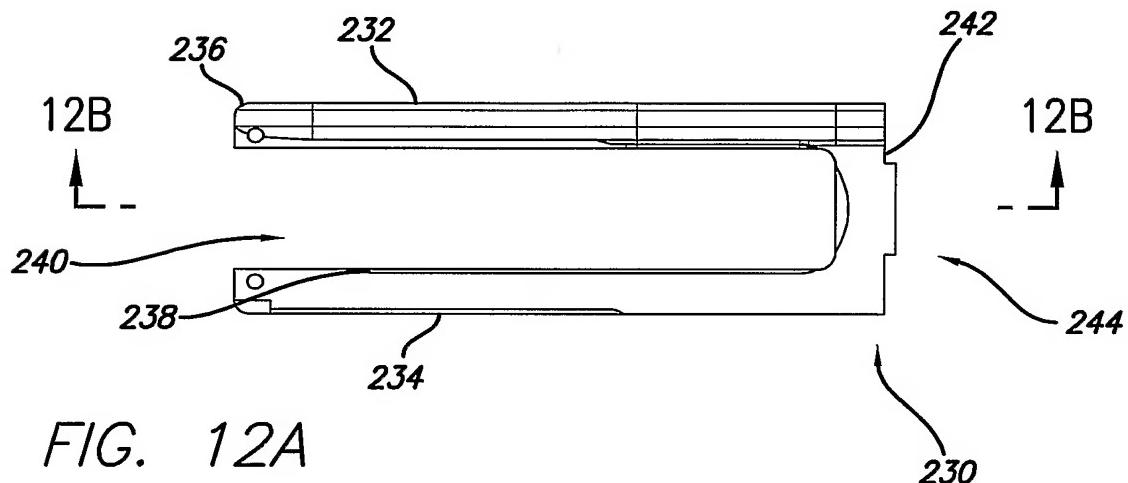


FIG. 12A

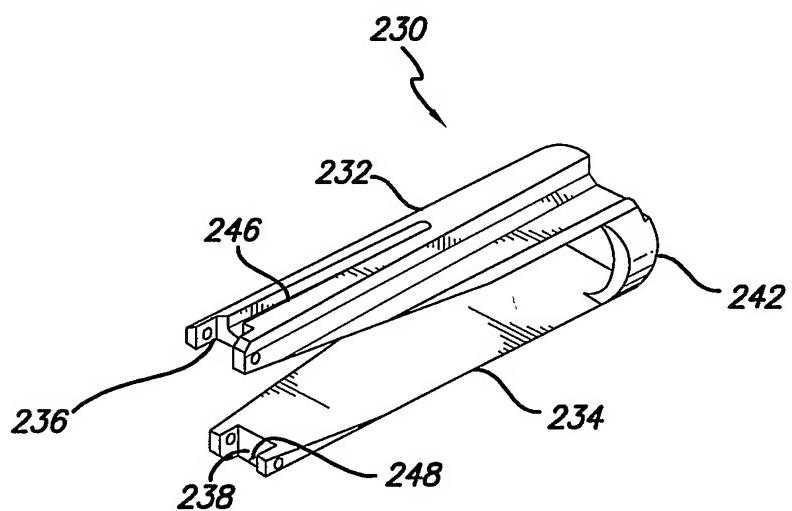


FIG. 12C

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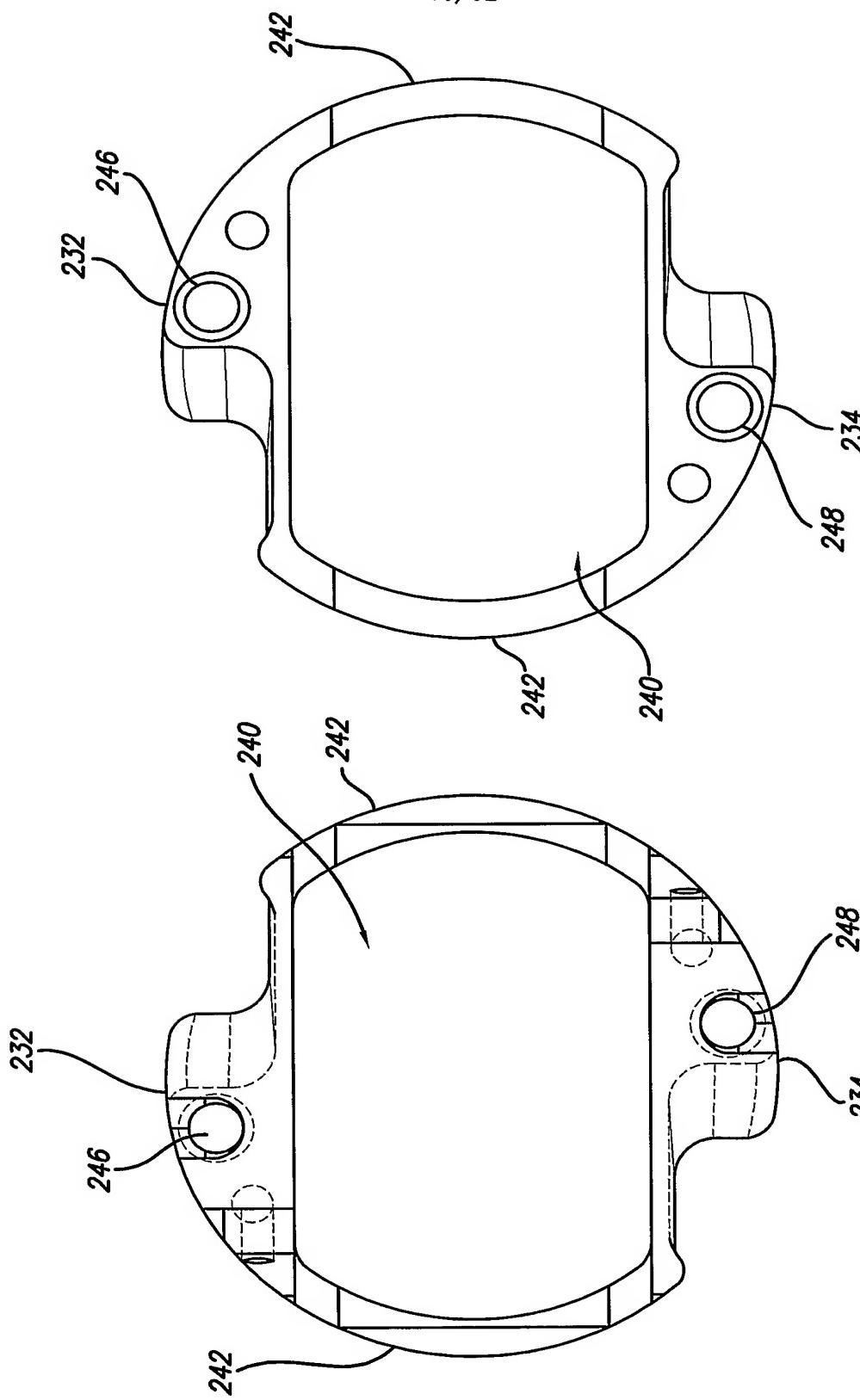


FIG. 12E
FIG. 12D

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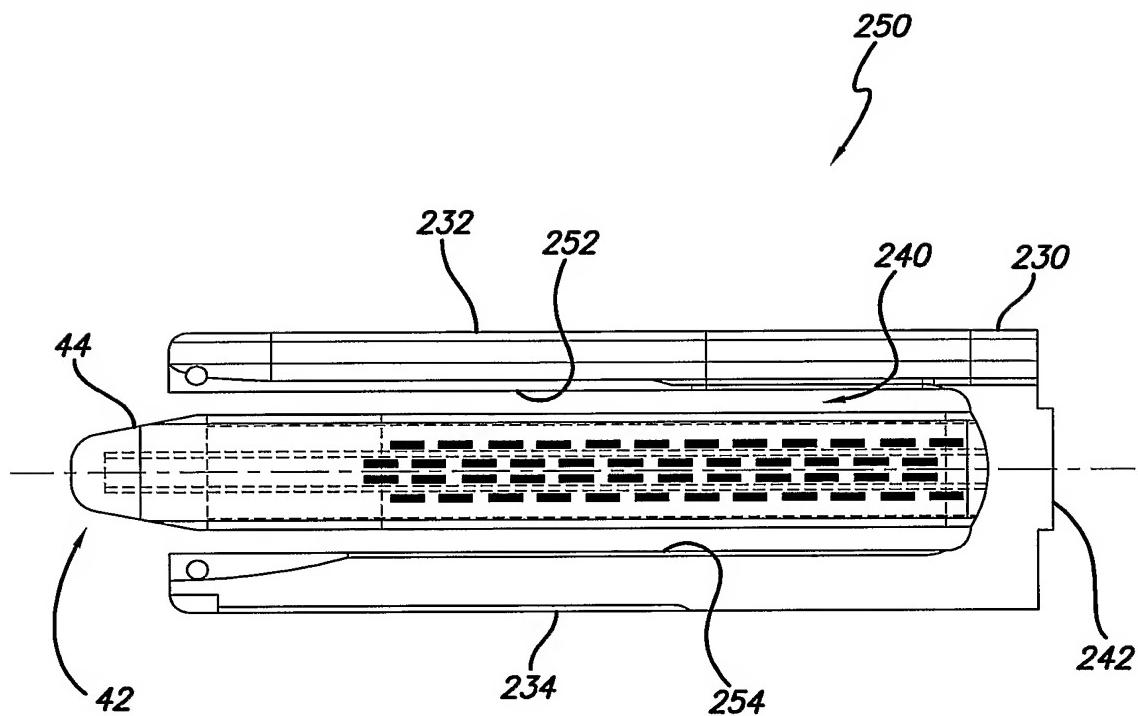


FIG. 13A

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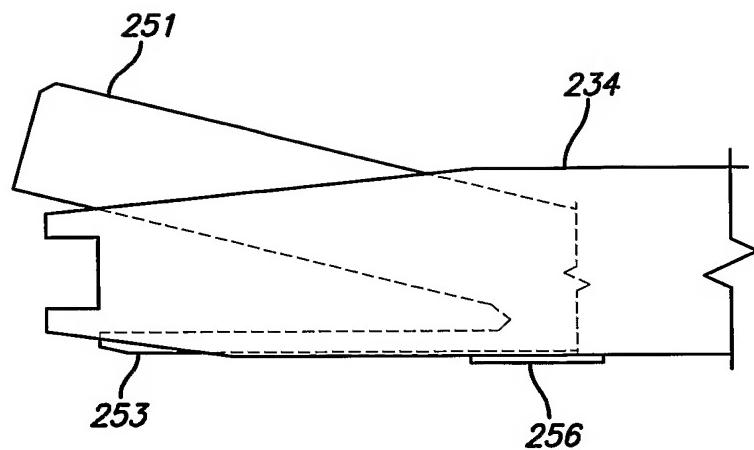


FIG. 13B

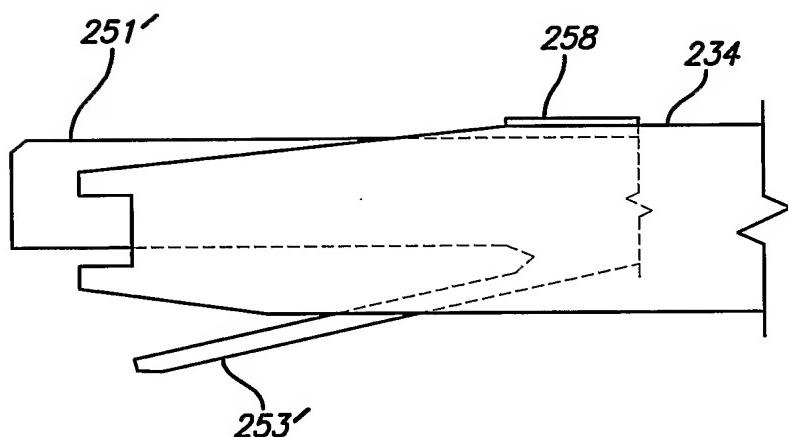


FIG. 13C

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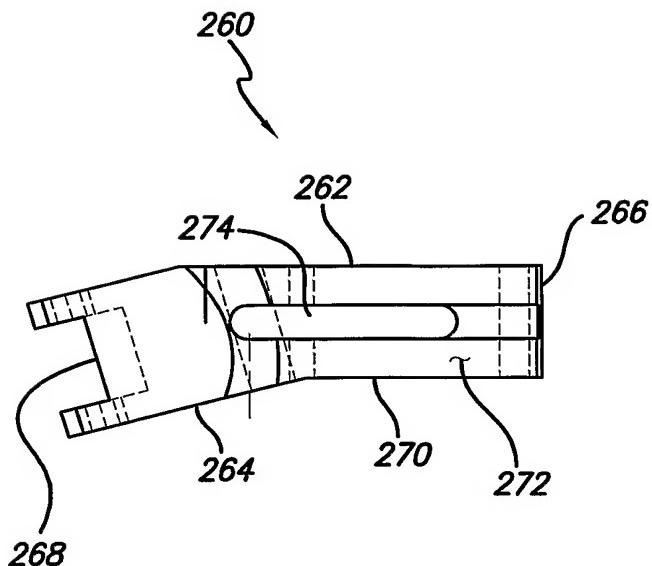


FIG. 14A

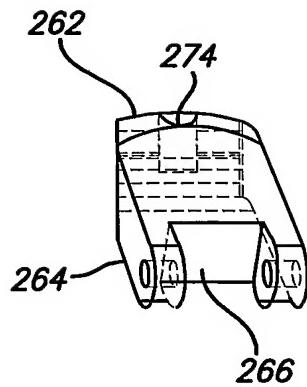


FIG. 14B

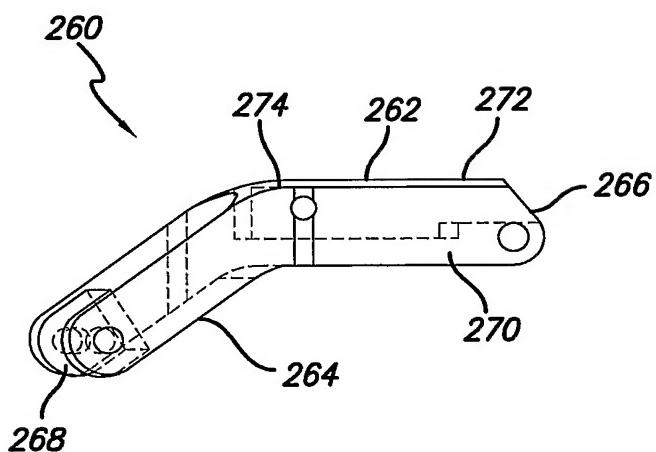


FIG. 14C

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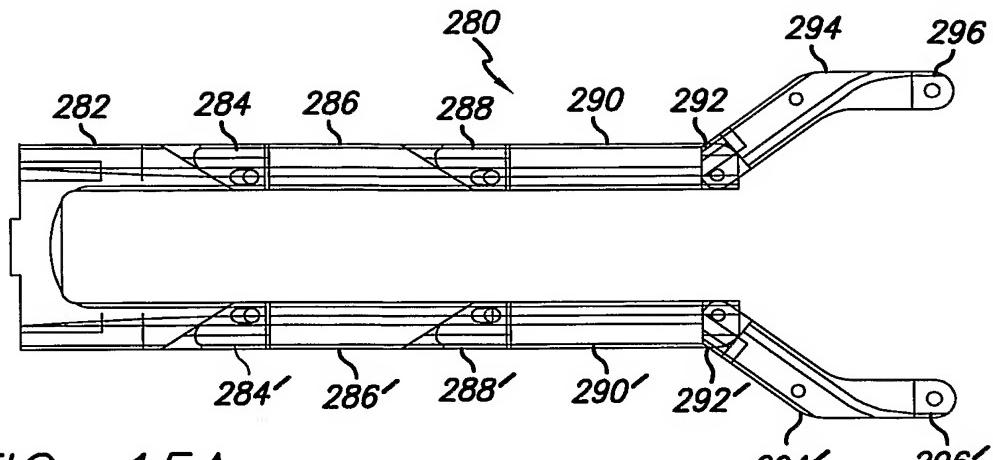


FIG. 15A

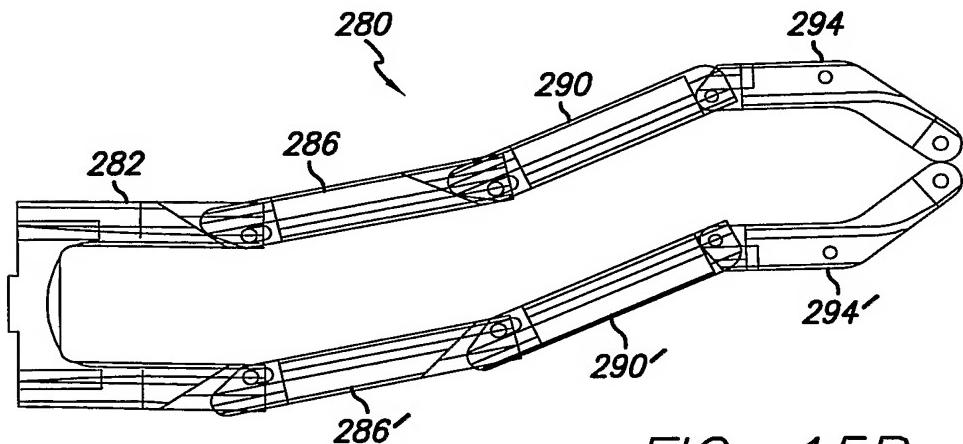


FIG. 15B

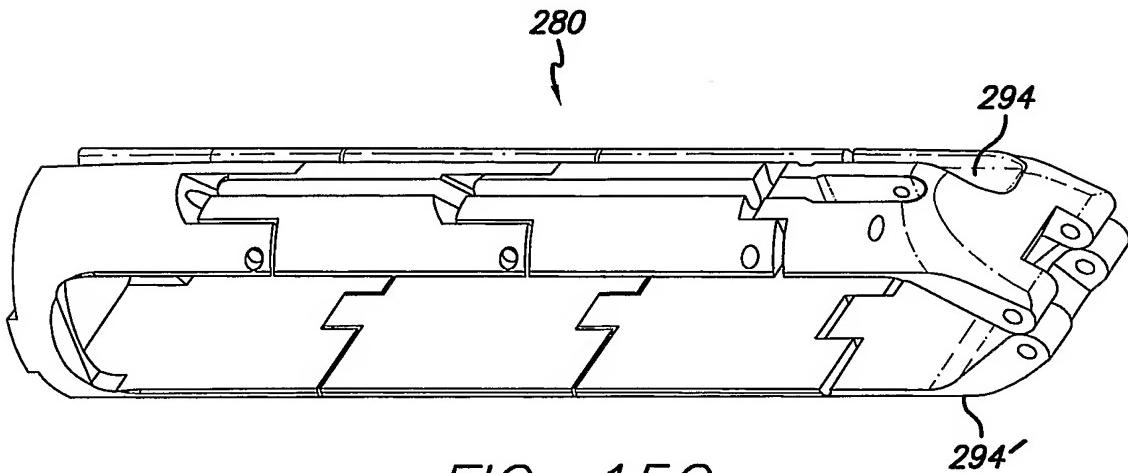


FIG. 15C

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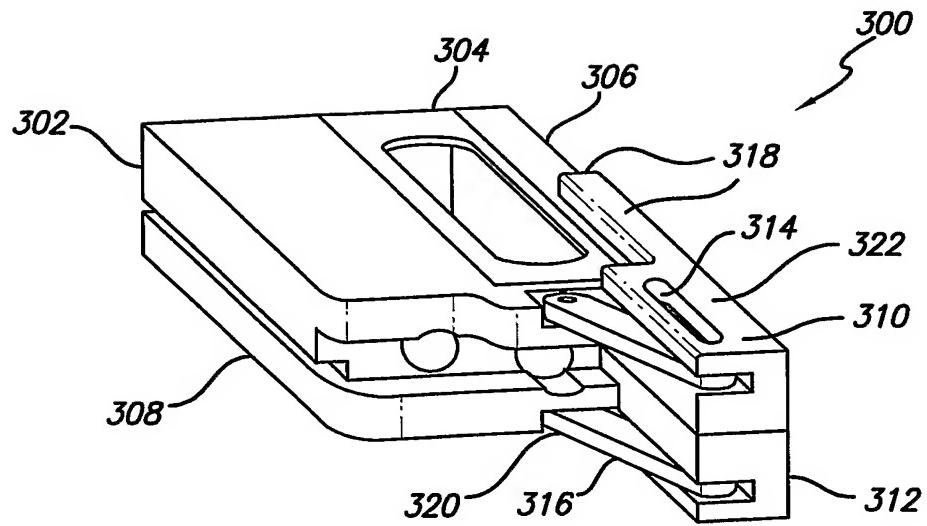


FIG. 16A

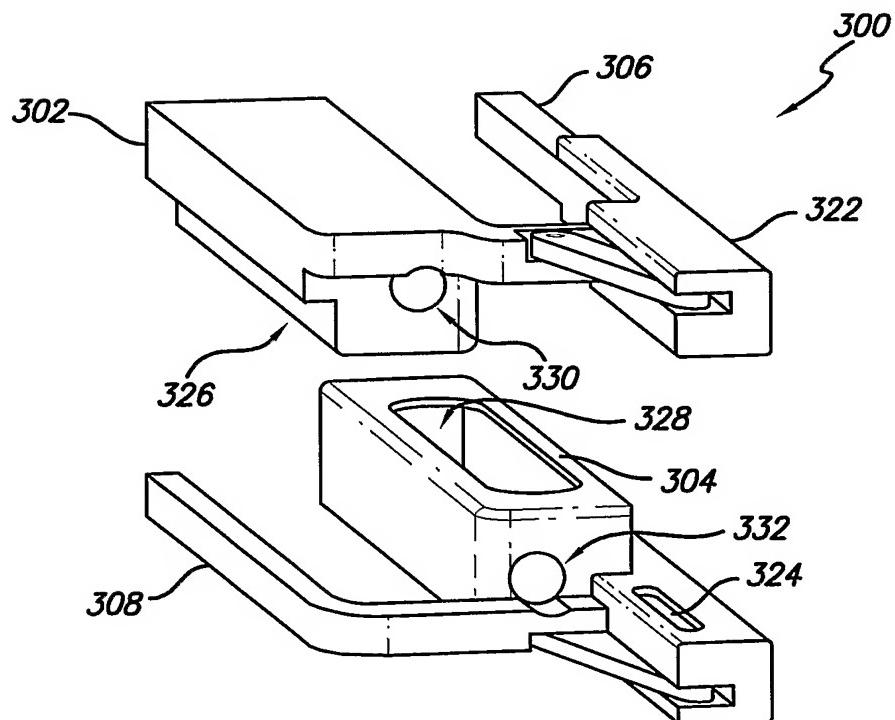


FIG. 16B

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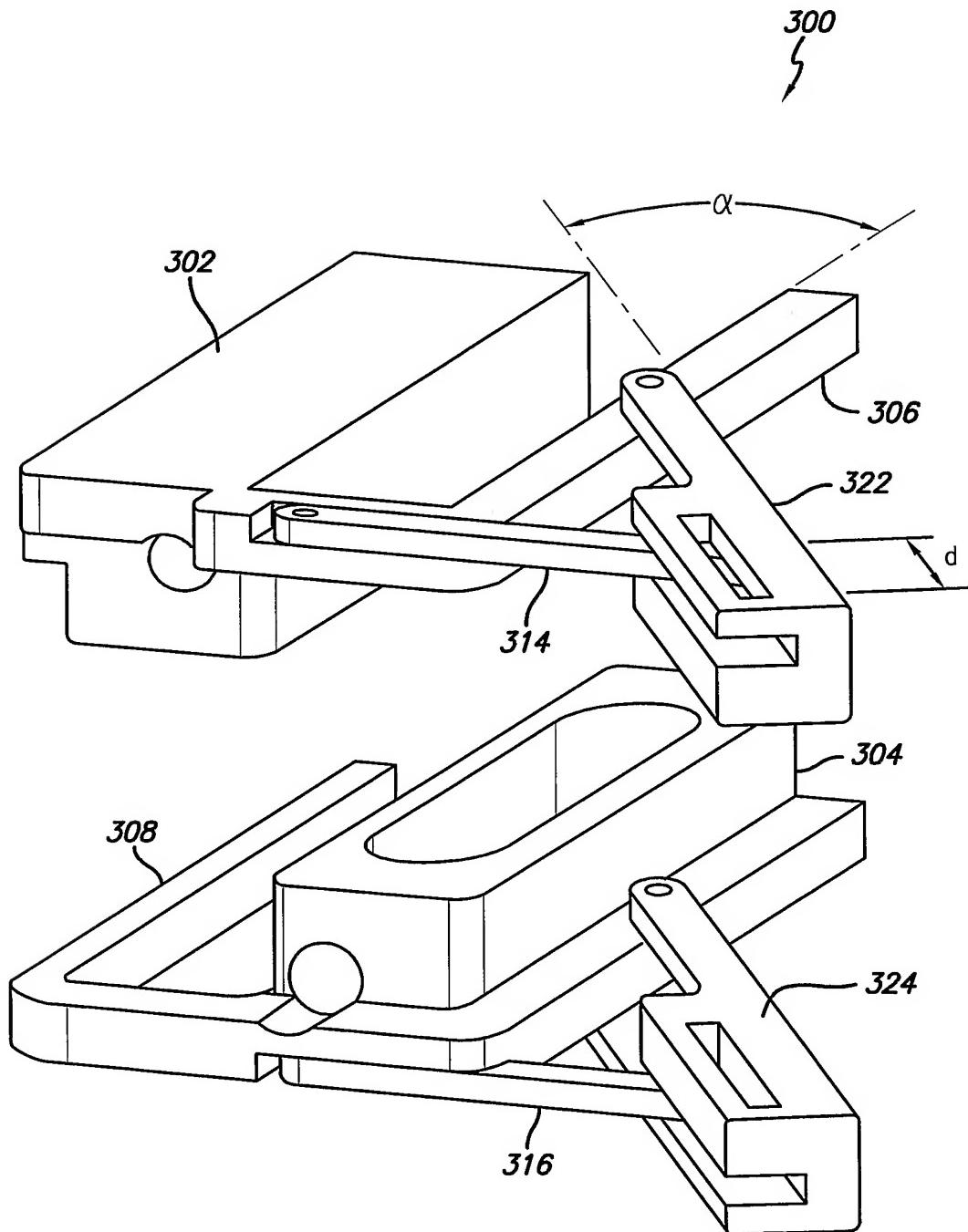
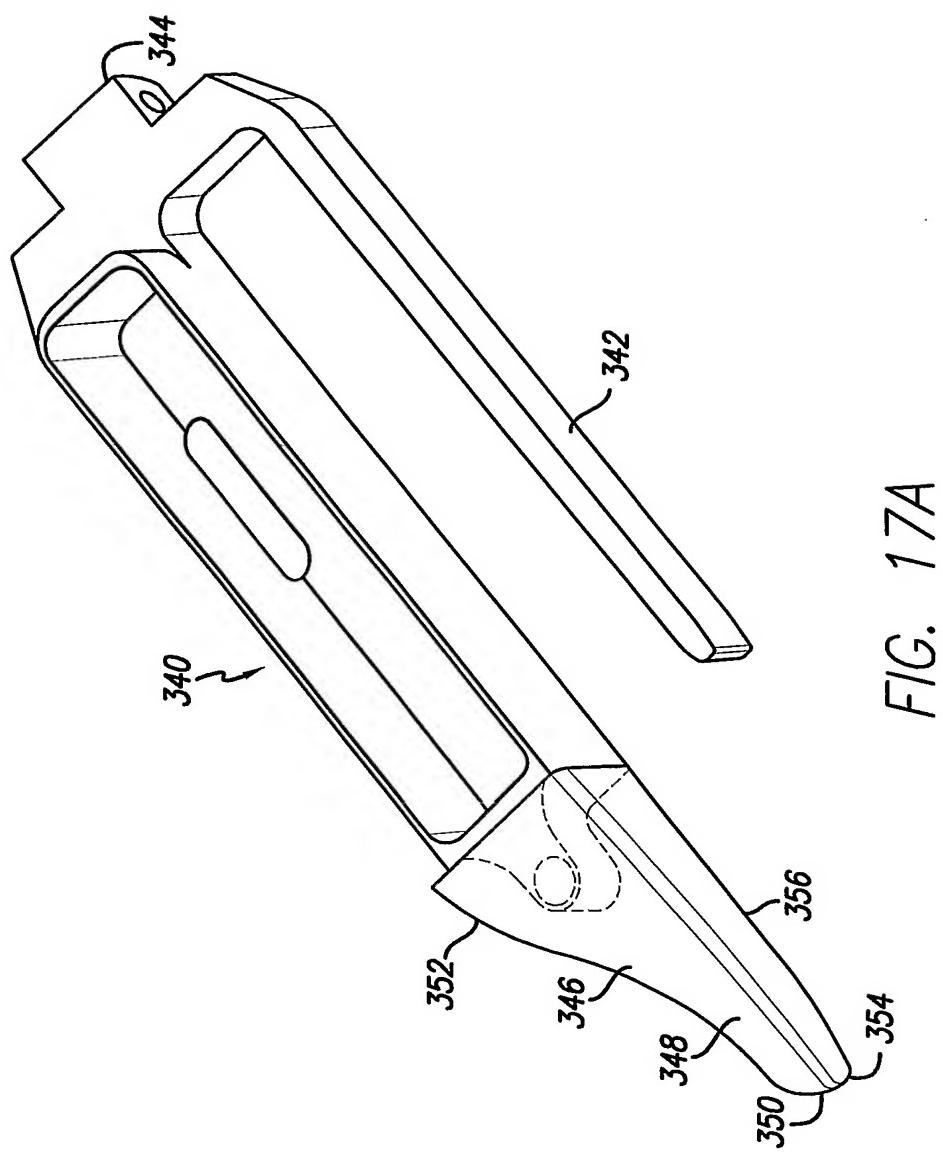


FIG. 16C

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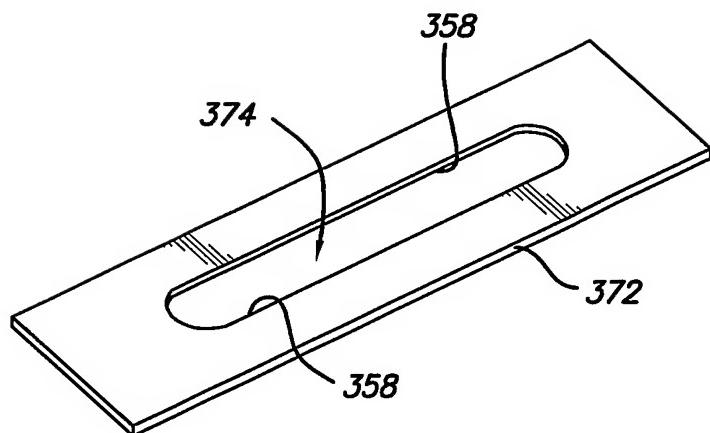


FIG. 17B

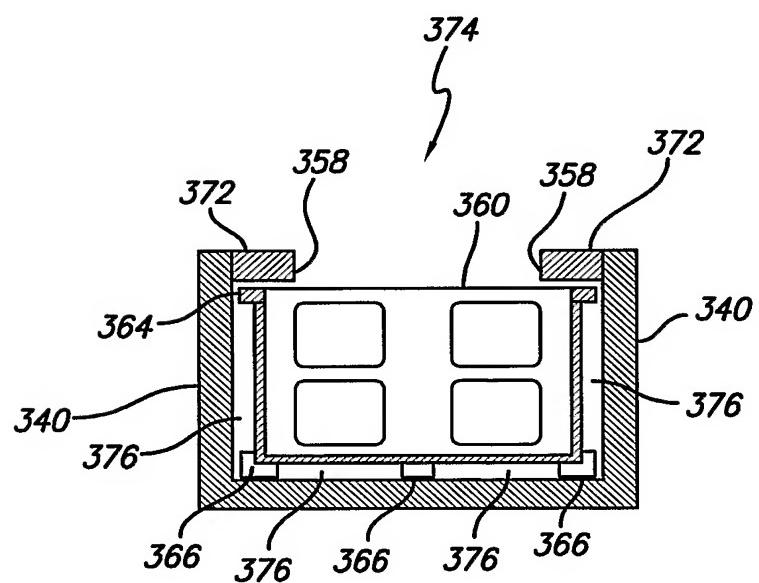


FIG. 17C

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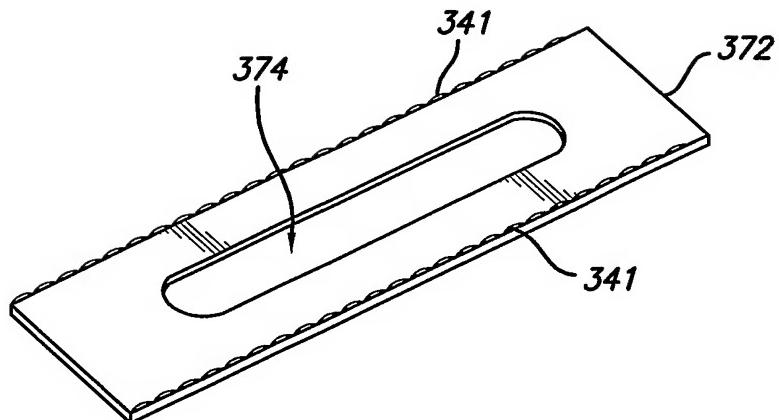


FIG. 17D

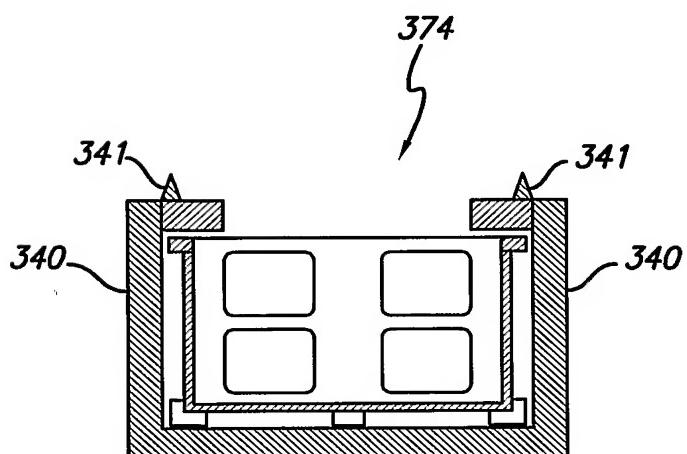


FIG. 17E

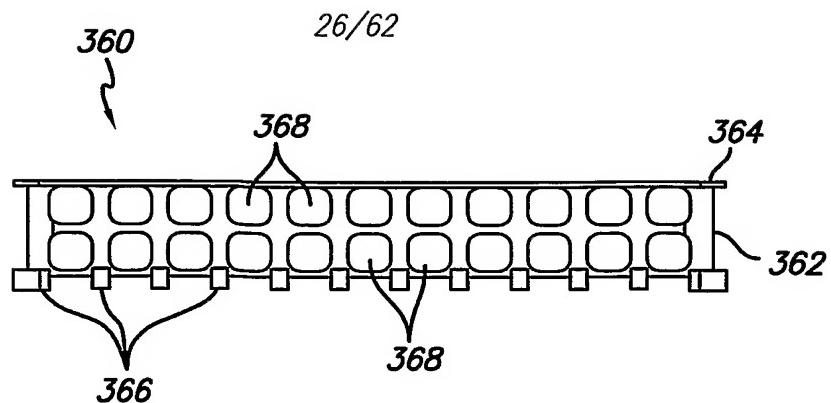


FIG. 18A

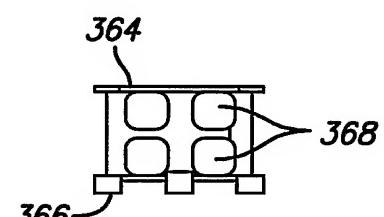


FIG. 18B

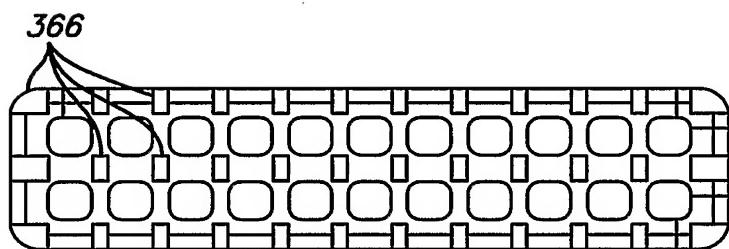


FIG. 18C

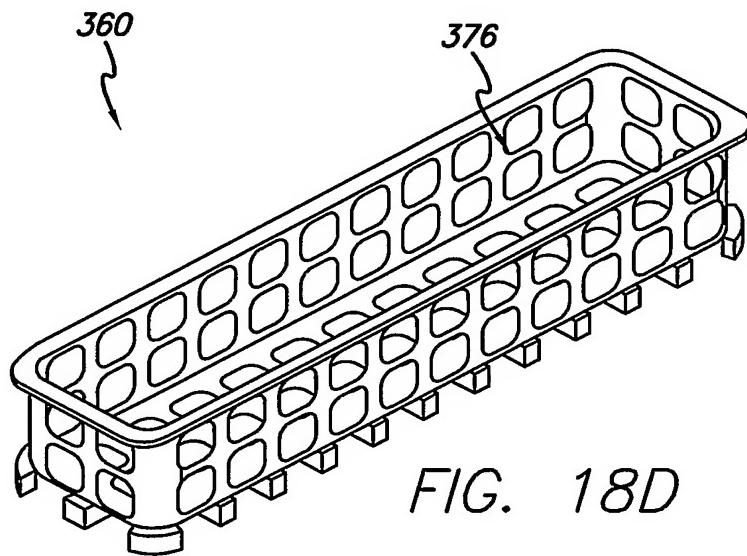


FIG. 18D

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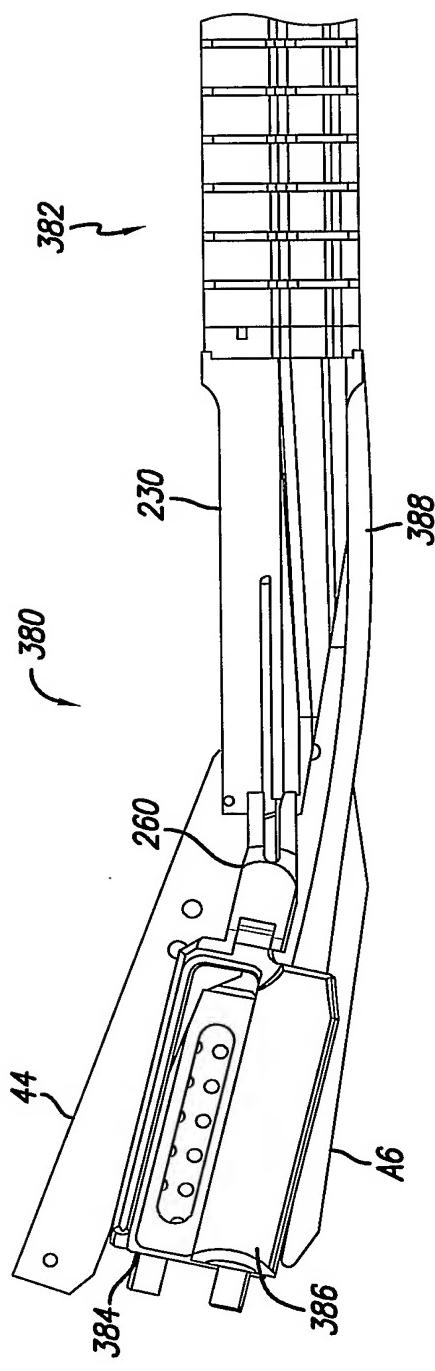


FIG. 19A

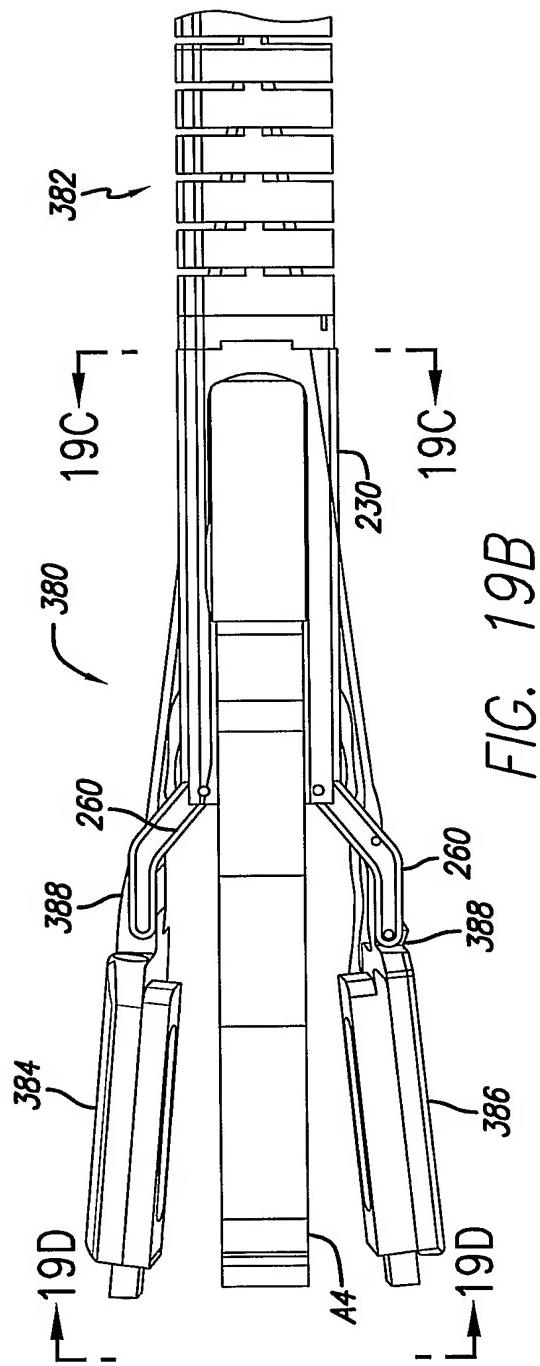


FIG. 19B

FIG. 19C

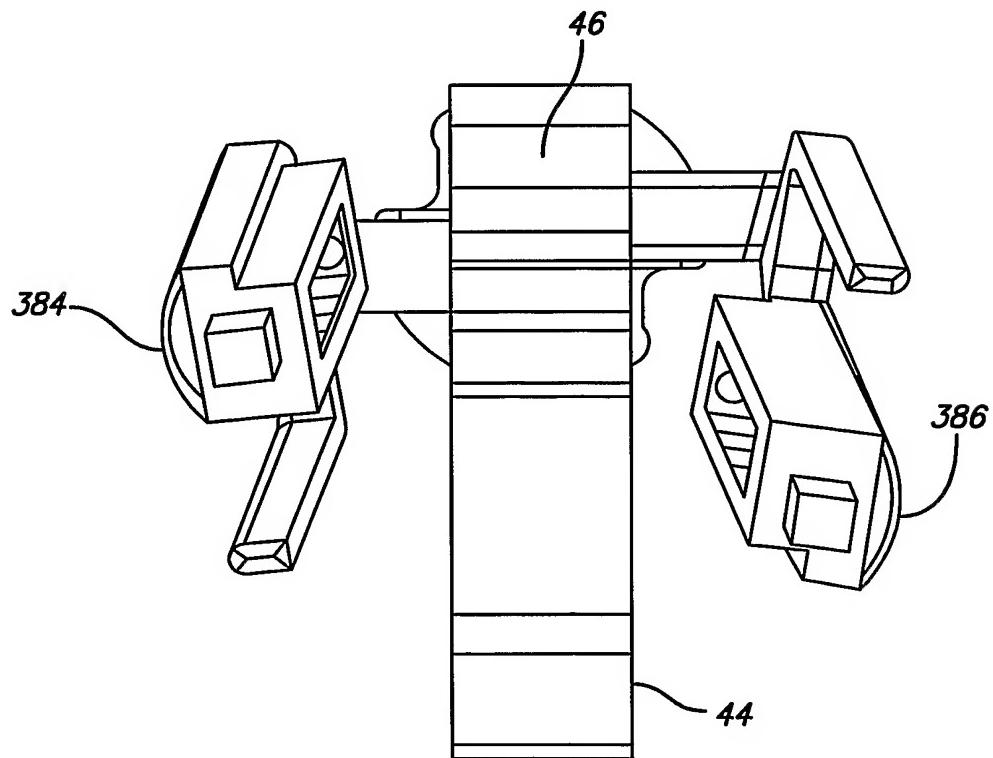
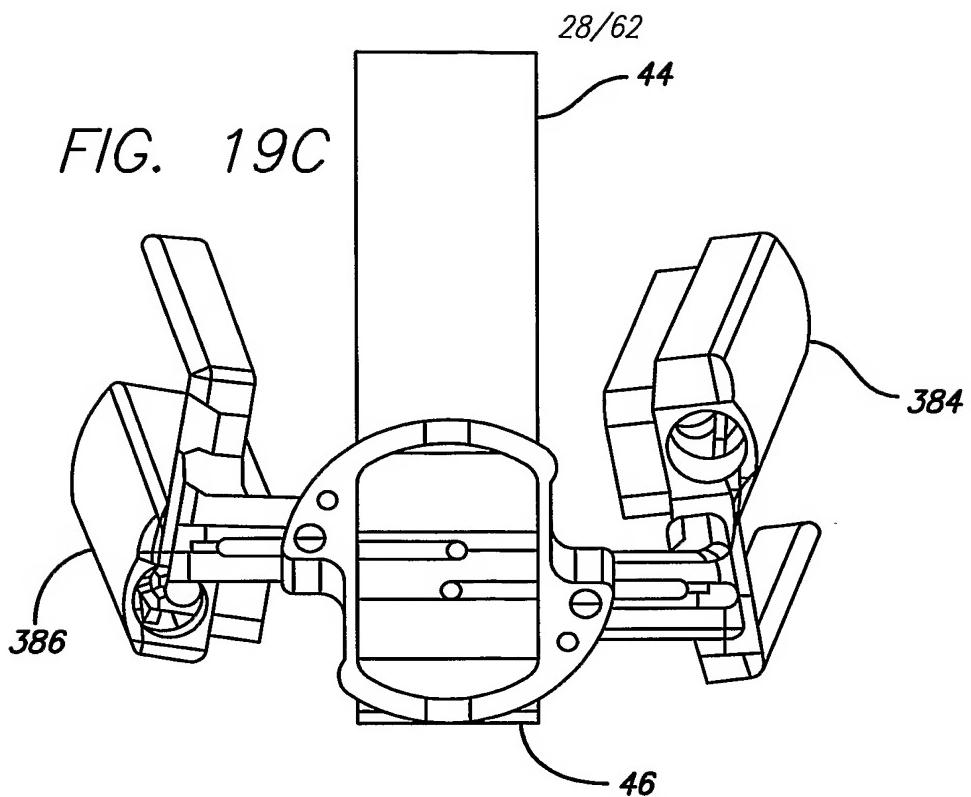


FIG. 19D

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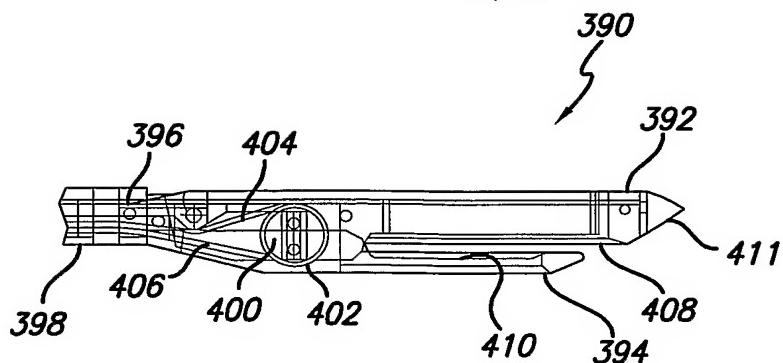


FIG. 20A

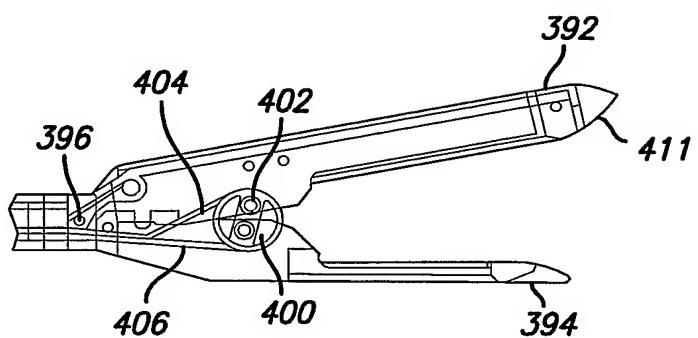


FIG. 20B

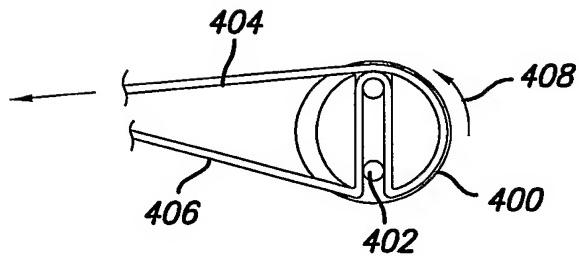


FIG. 21A

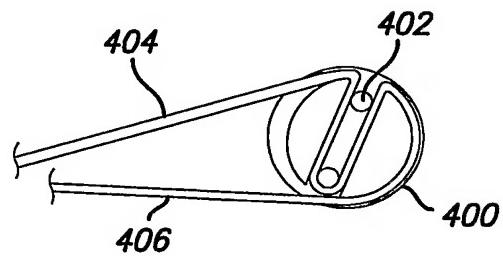


FIG. 21B

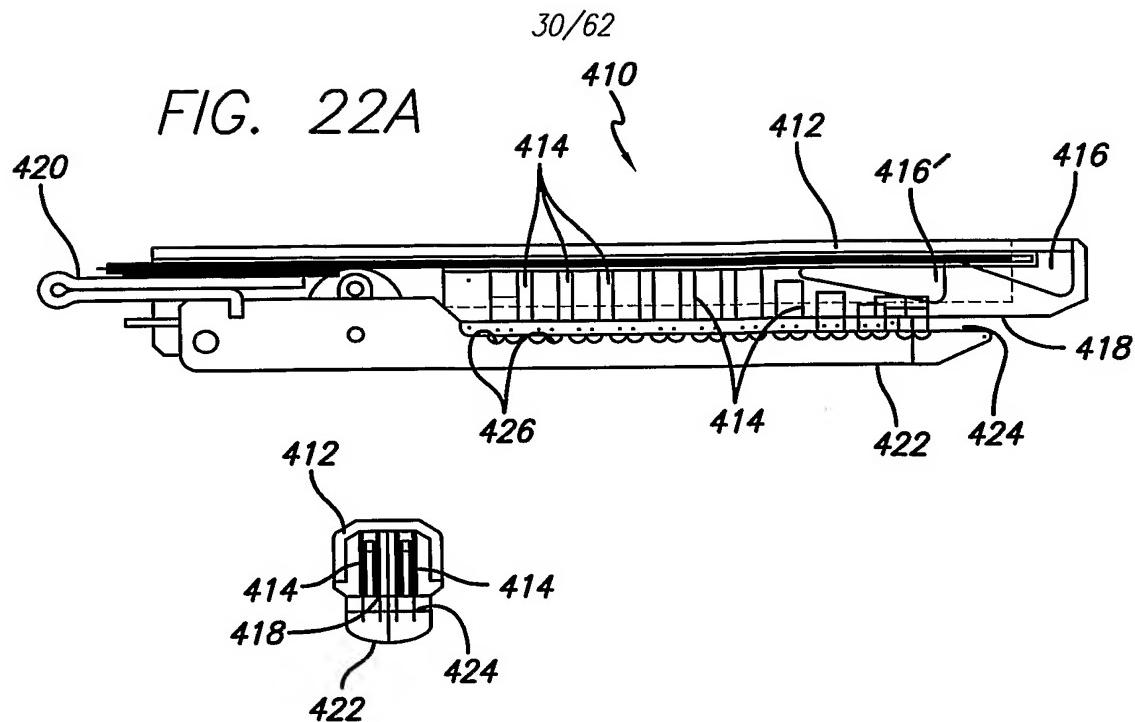


FIG. 22B

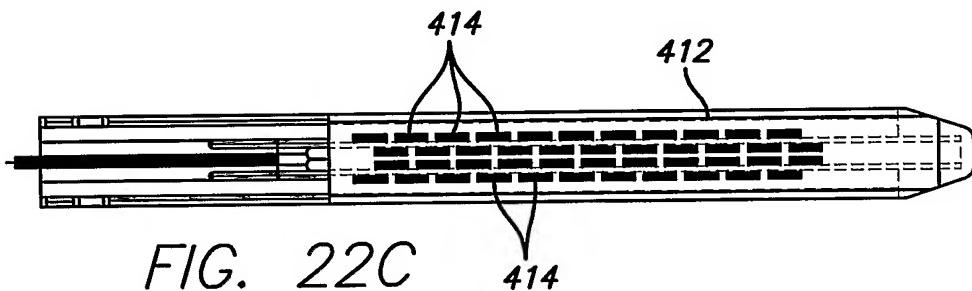


FIG. 22C

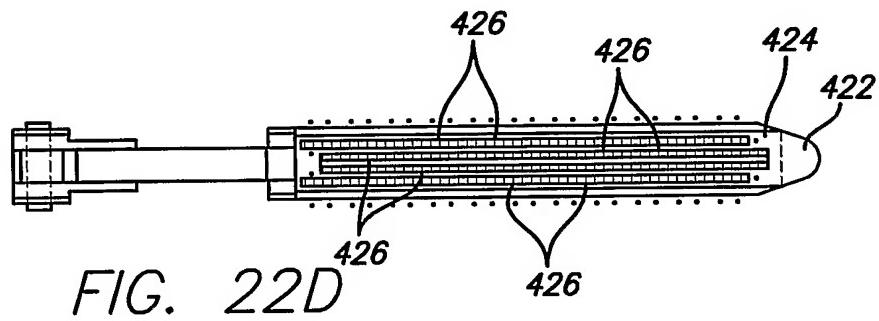


FIG. 22D

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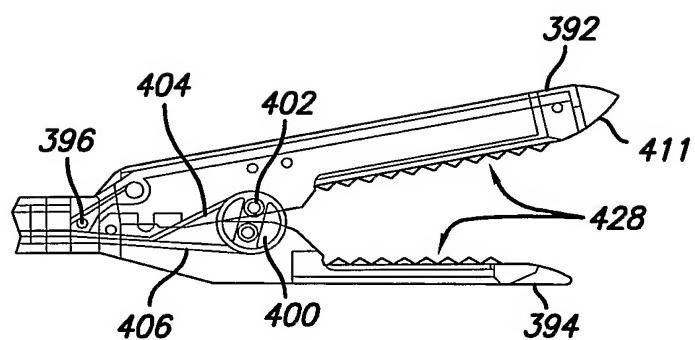


FIG. 22E

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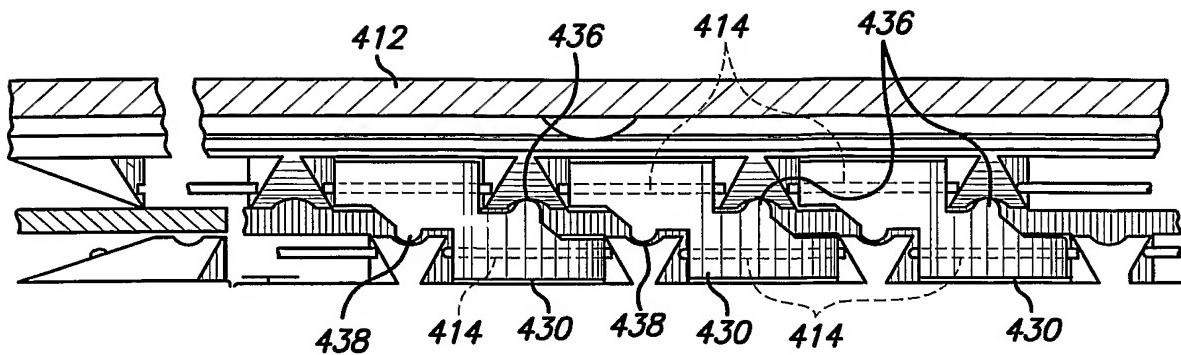


FIG. 23A

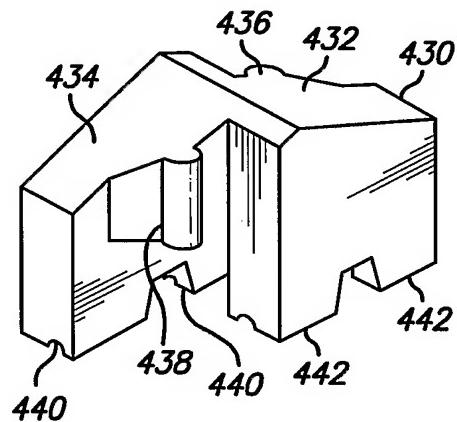


FIG. 23B

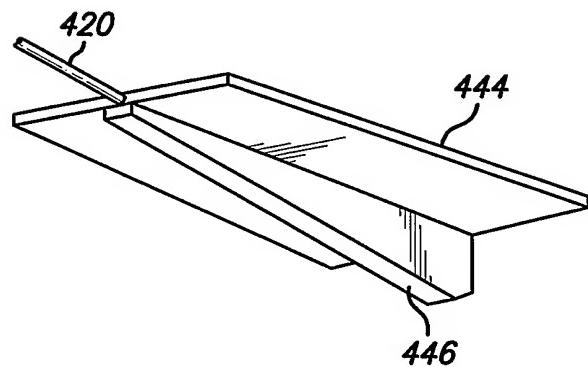


FIG. 23C

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FIG. 24A

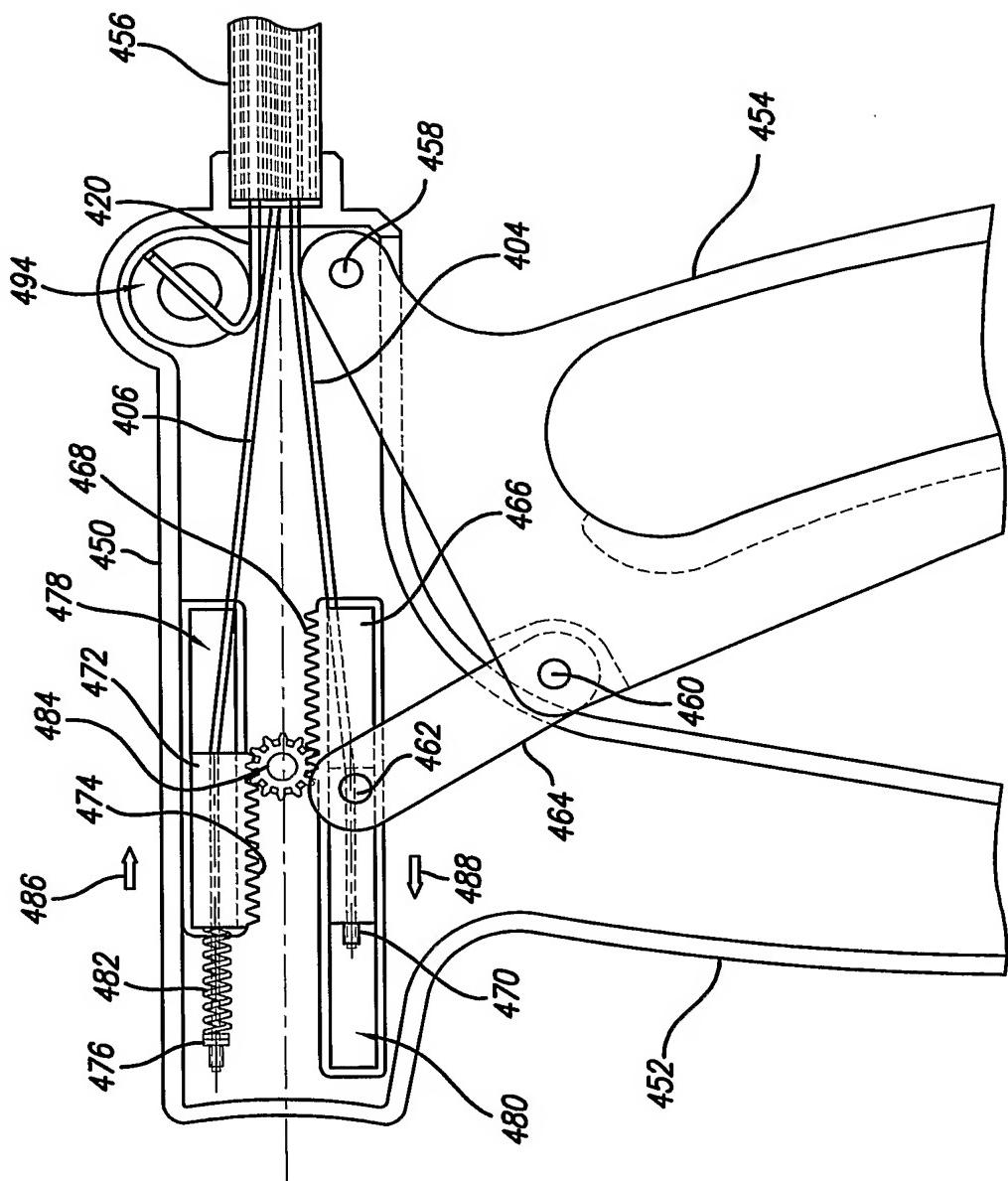
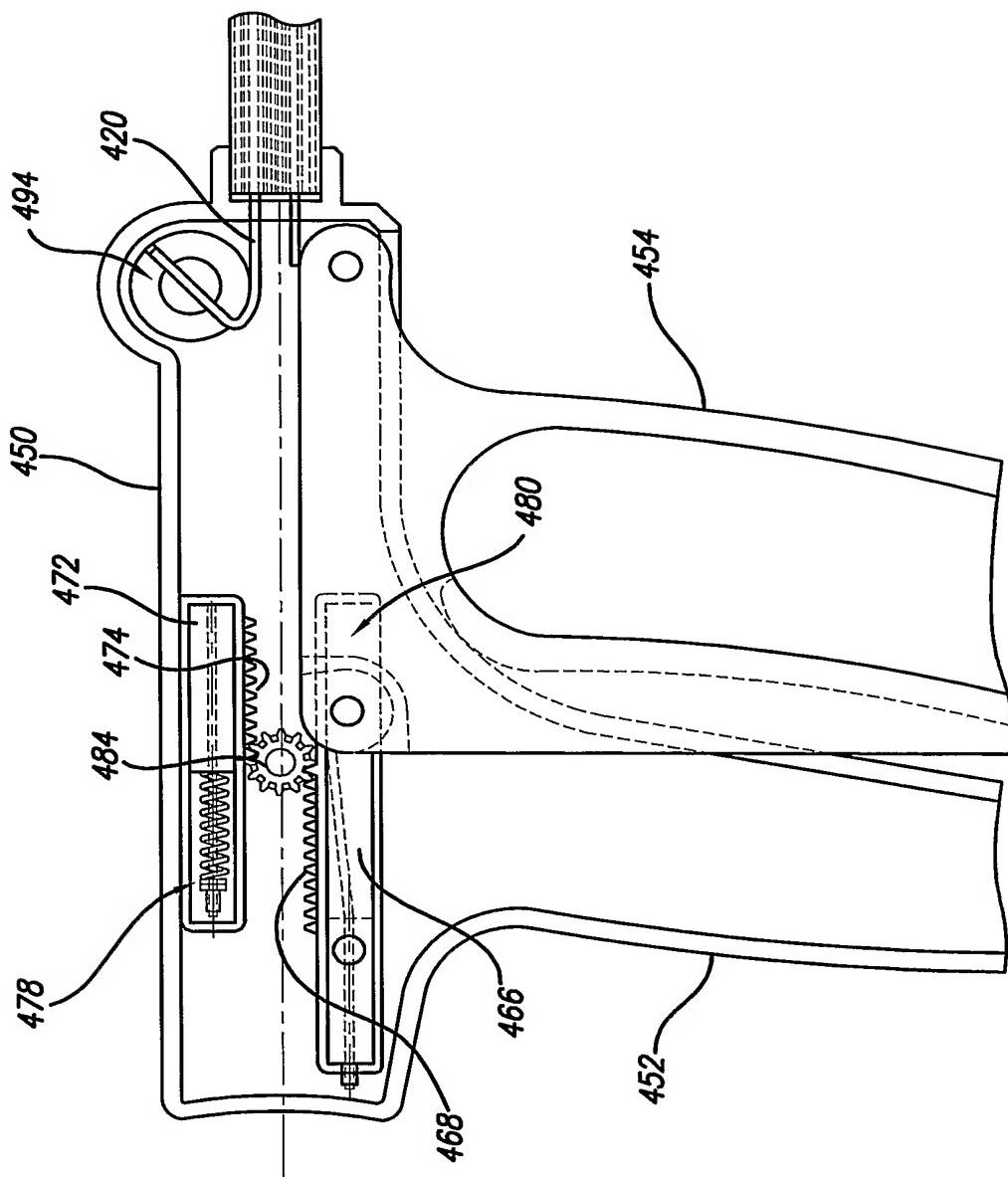


FIG. 24B



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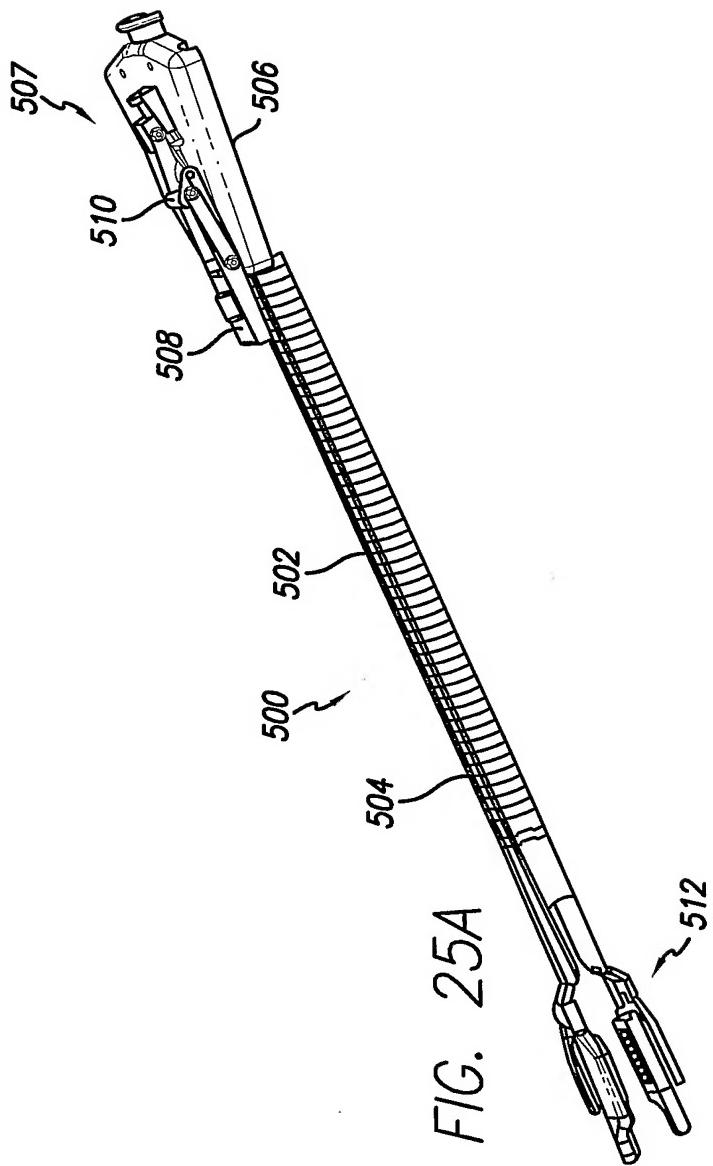


FIG. 25A

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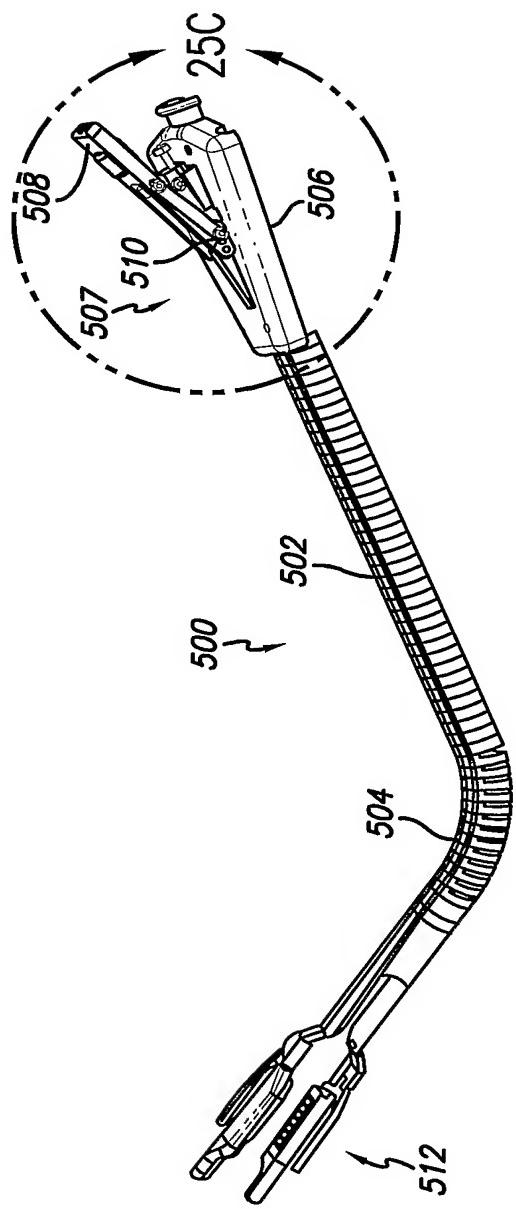


FIG. 25B

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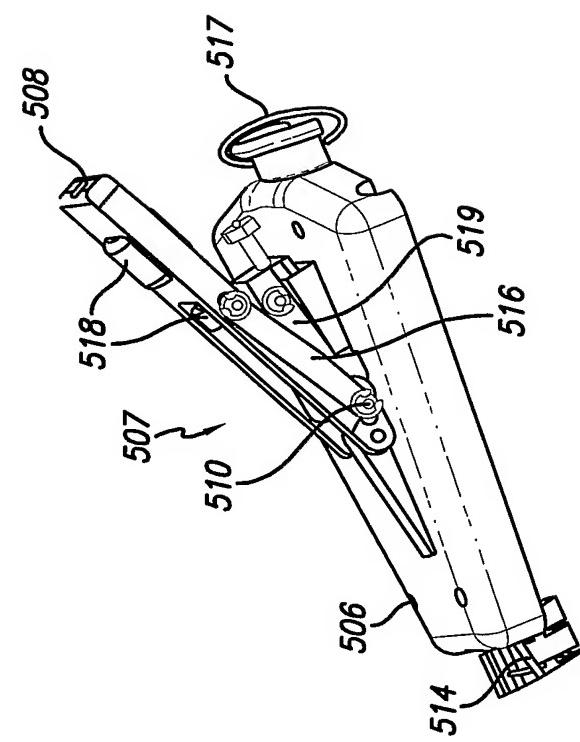


FIG. 25C

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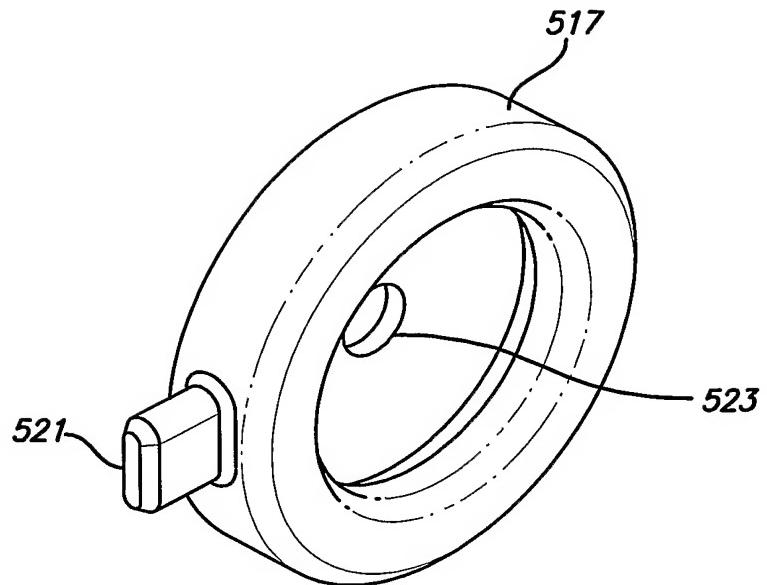


FIG. 25D

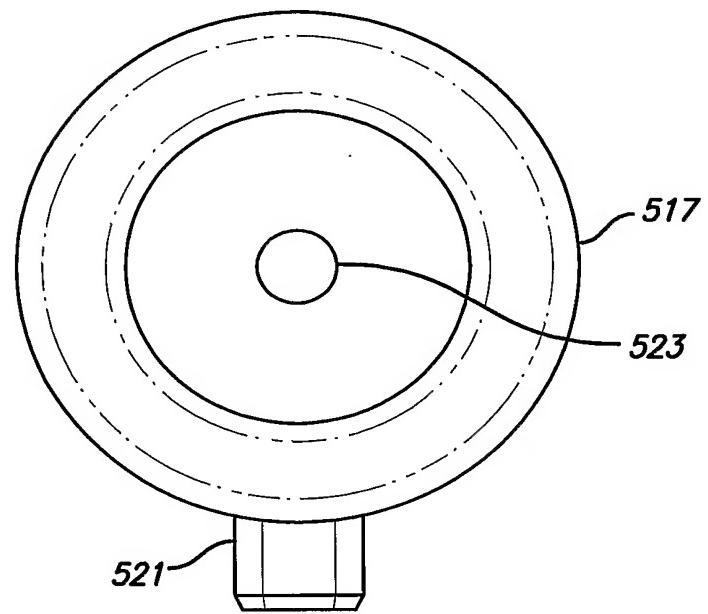


FIG. 25E

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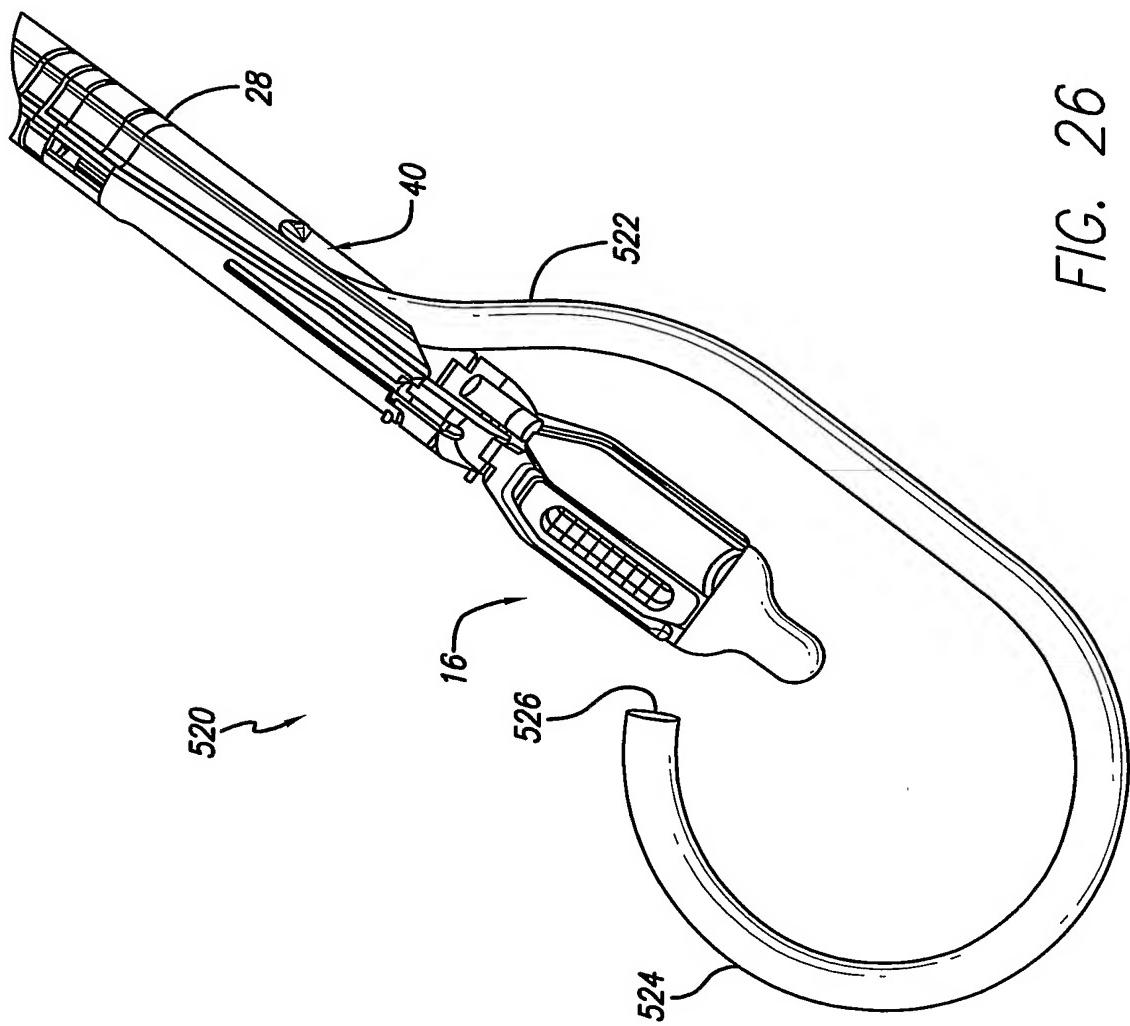


FIG. 26

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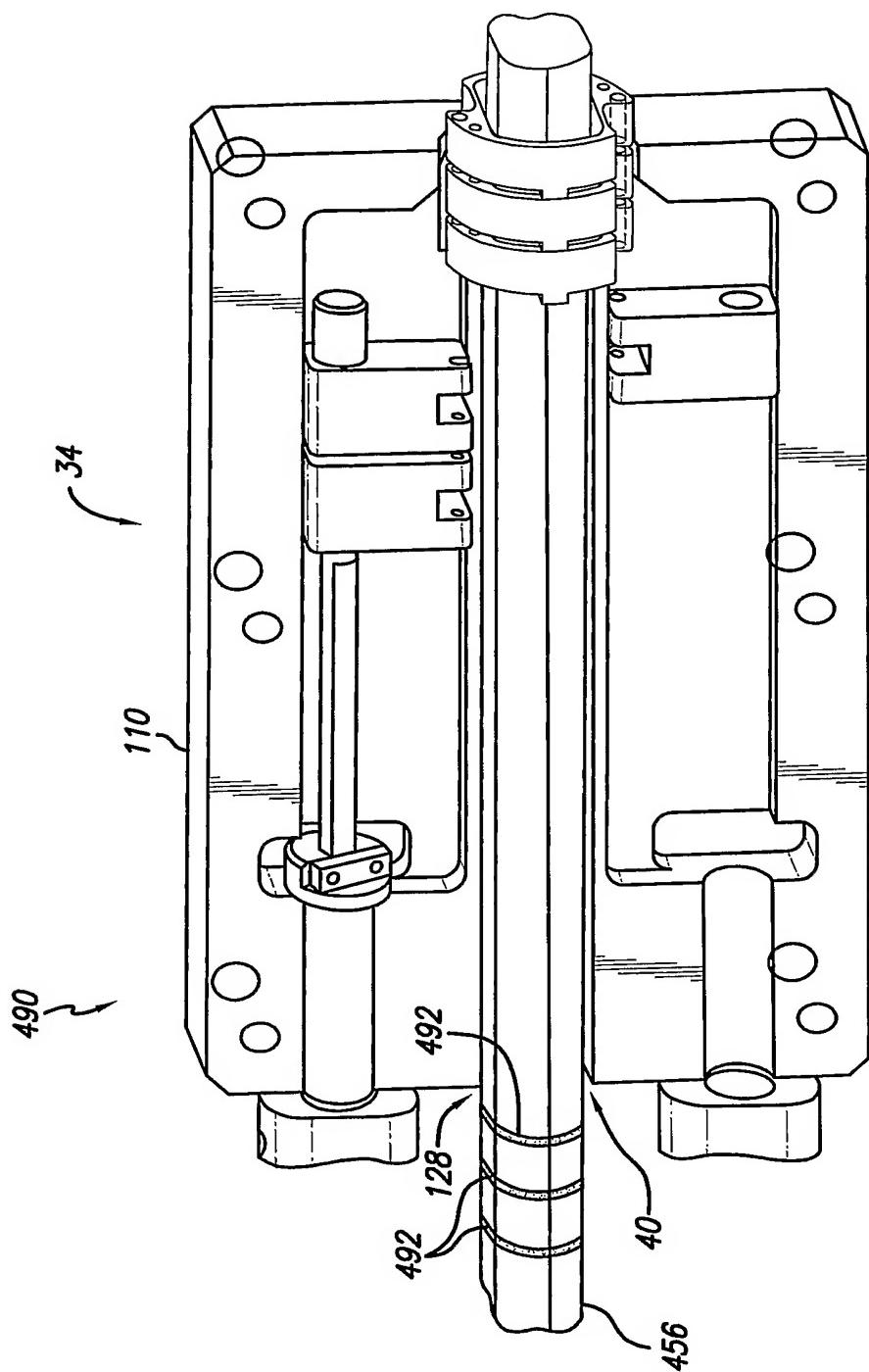
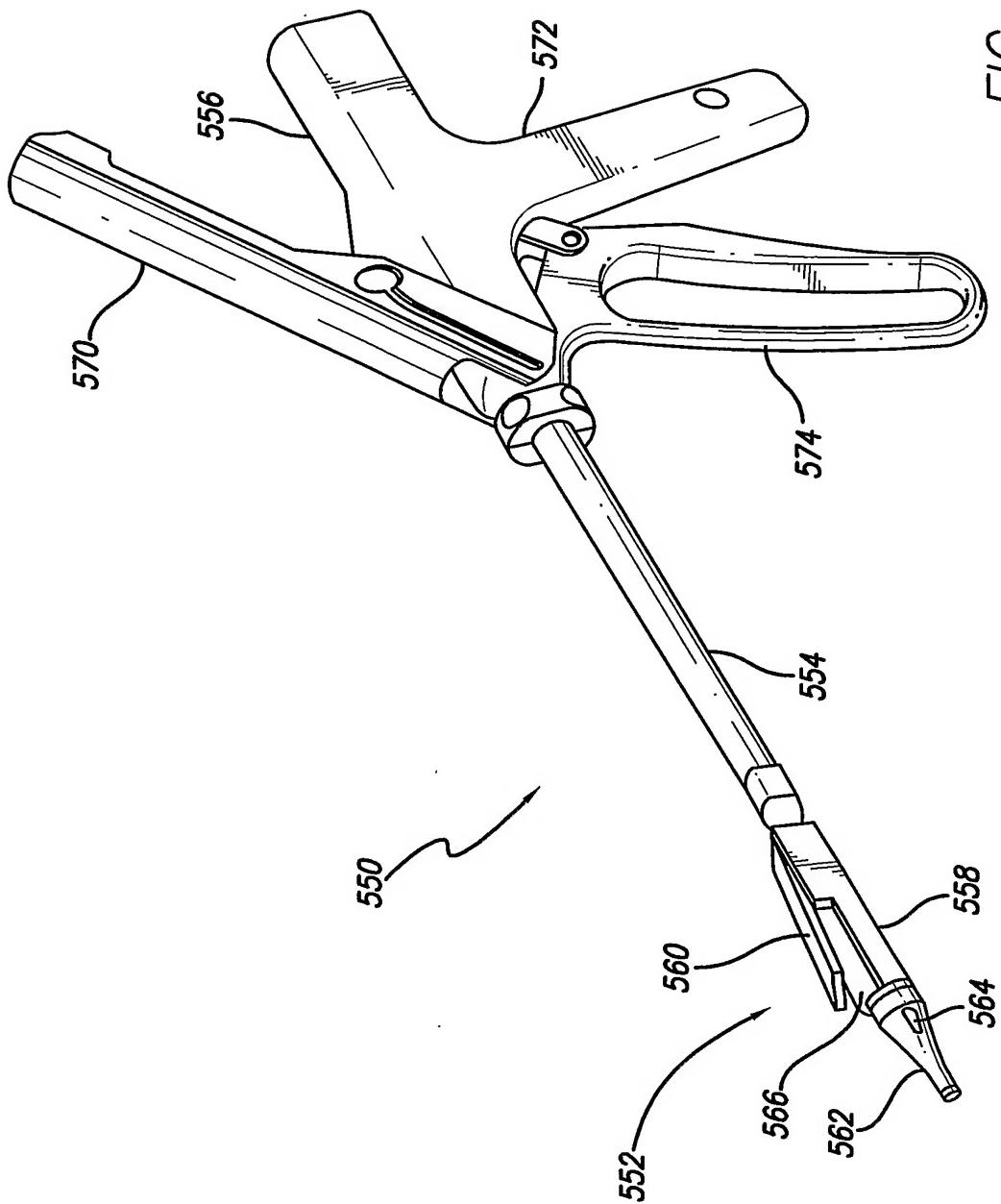


FIG. 27

FIG. 28



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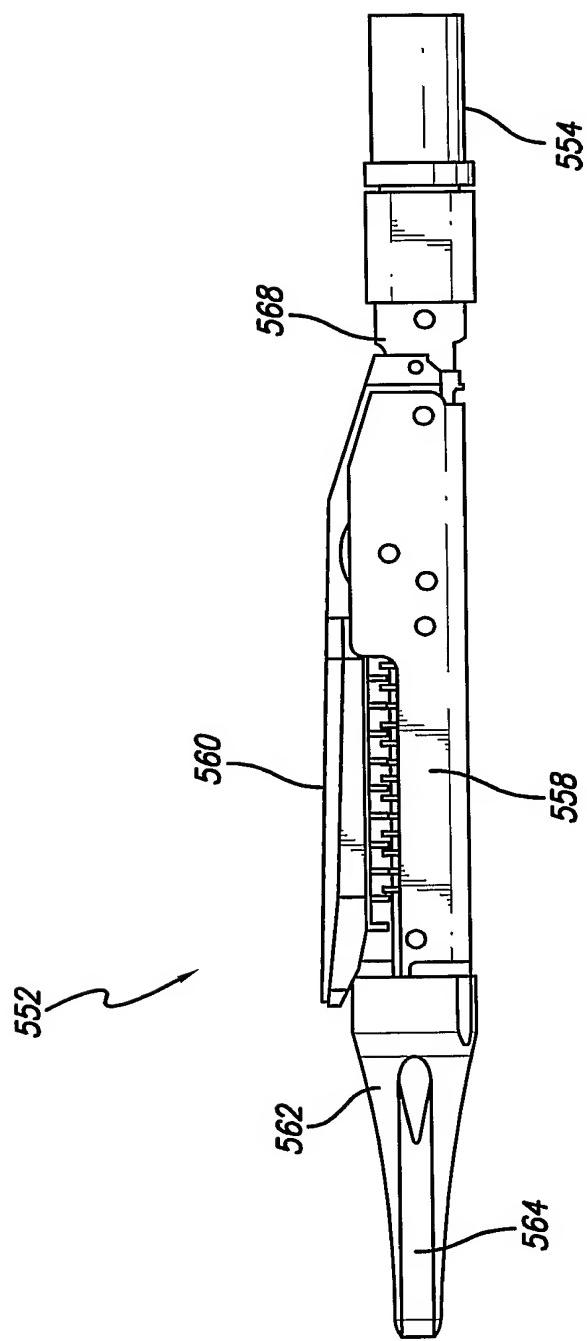
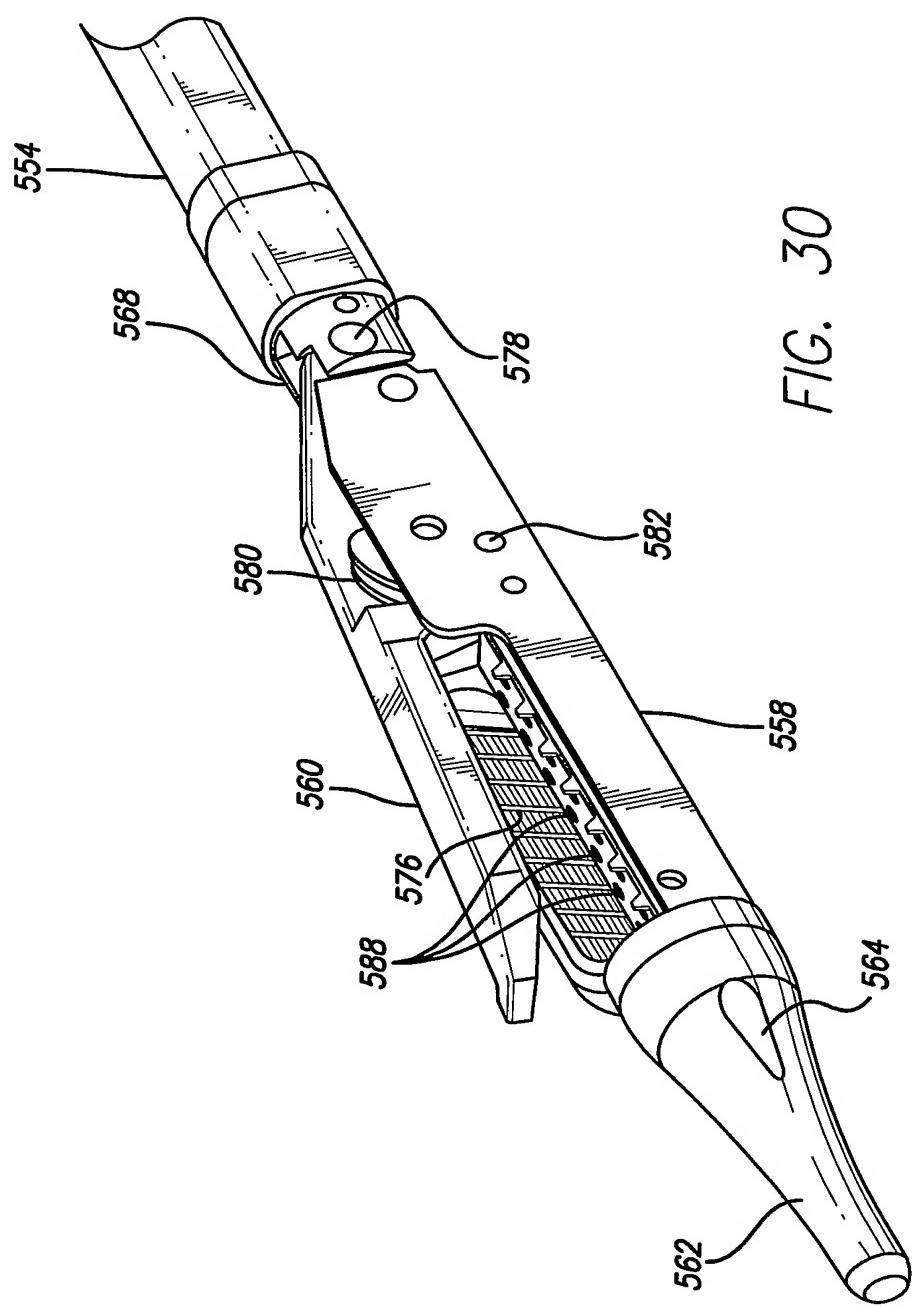


FIG. 29

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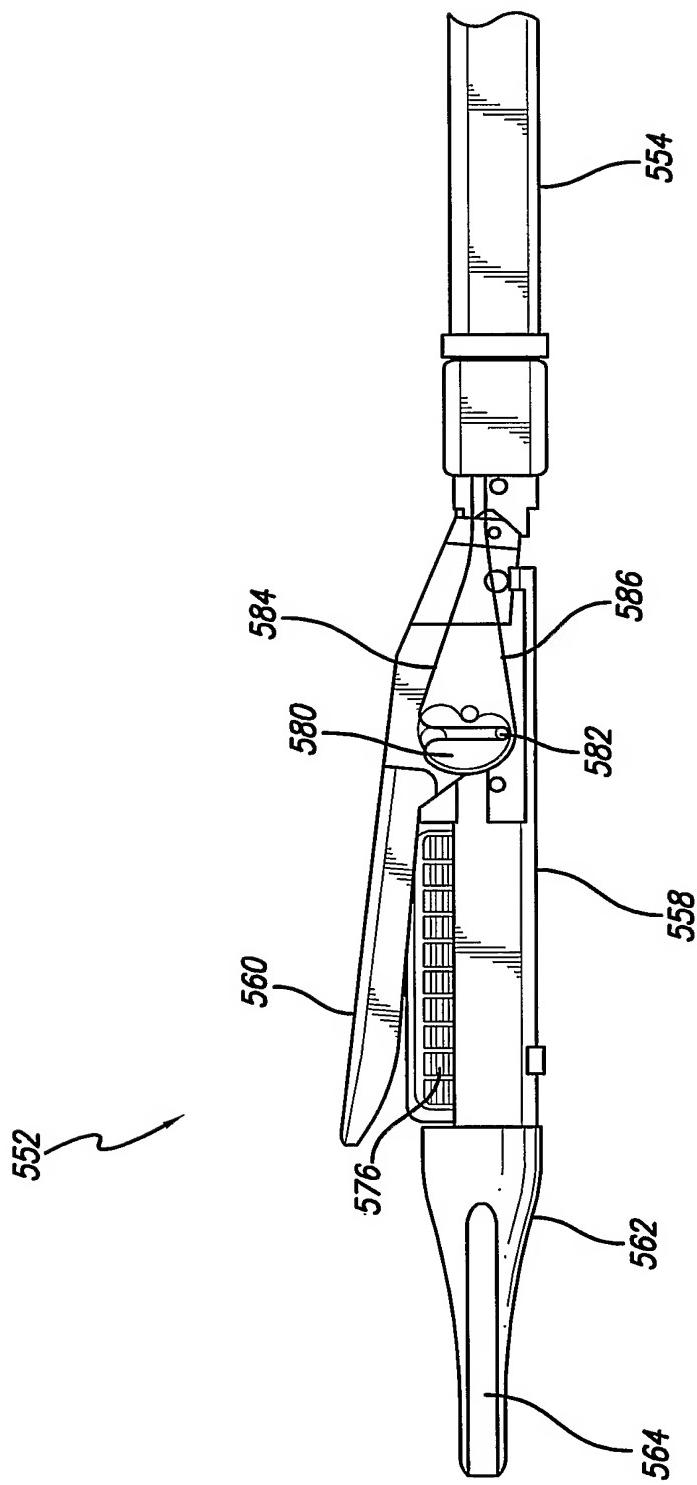
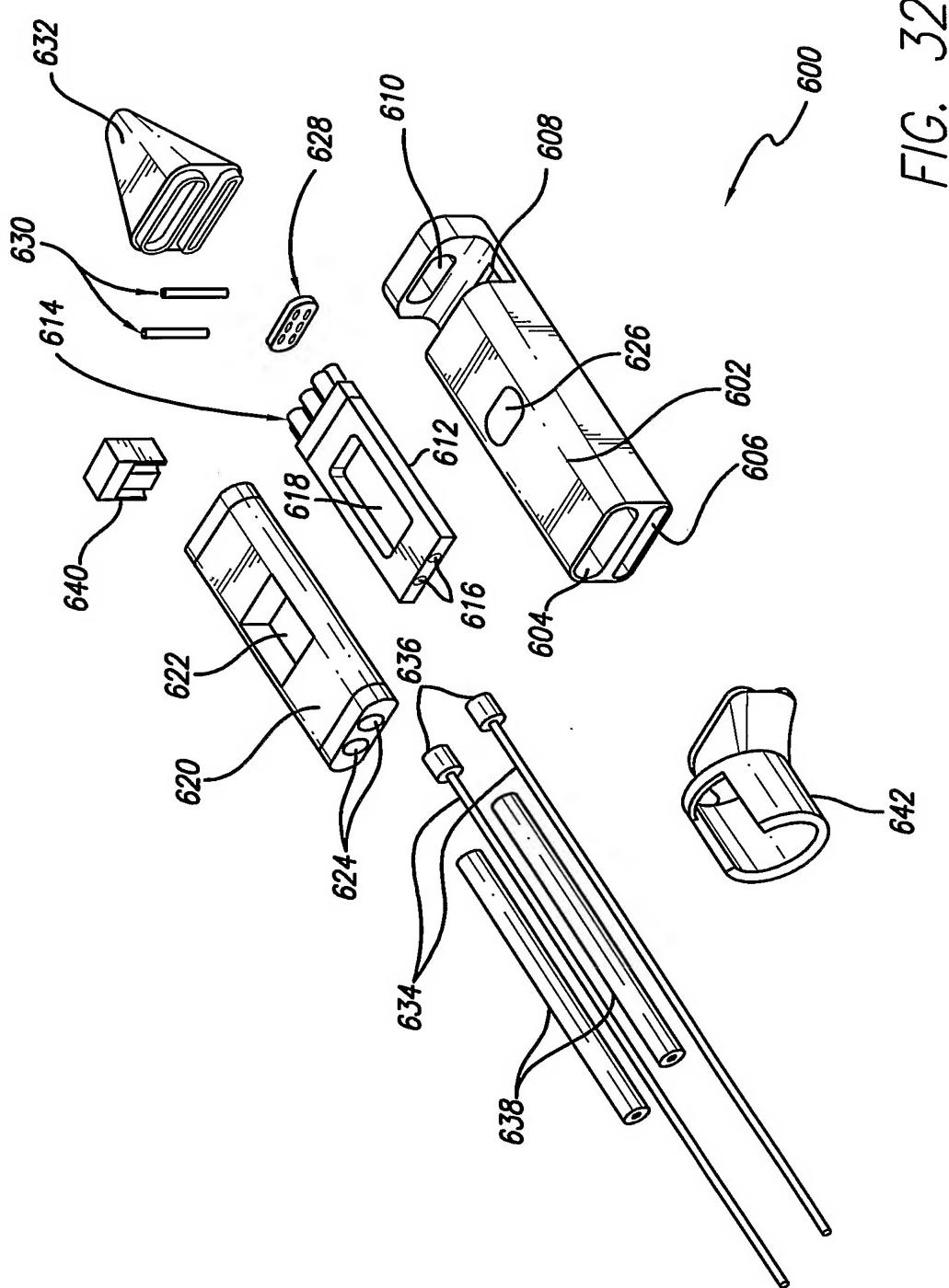


FIG. 31



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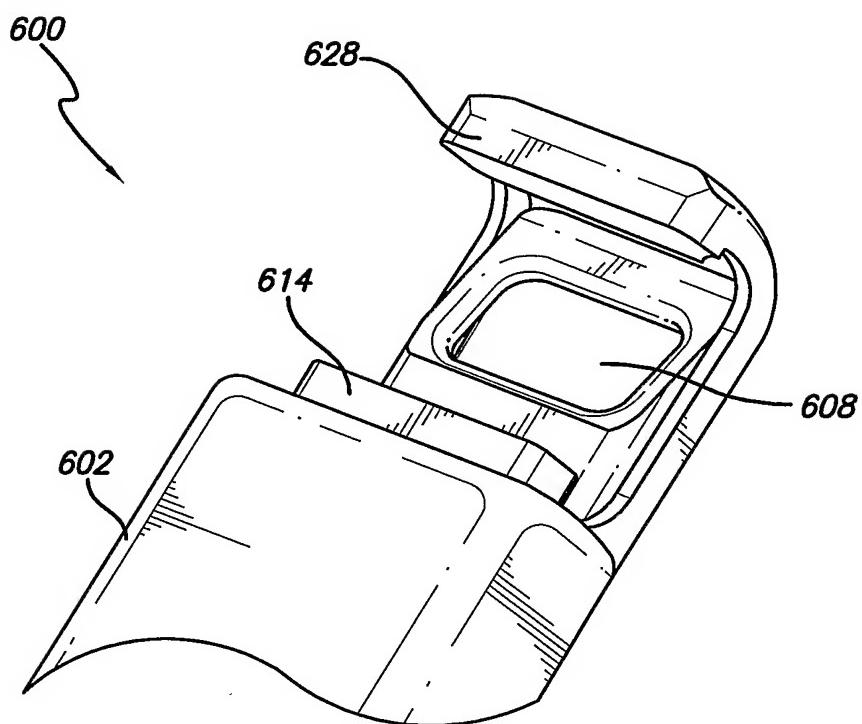


FIG. 33

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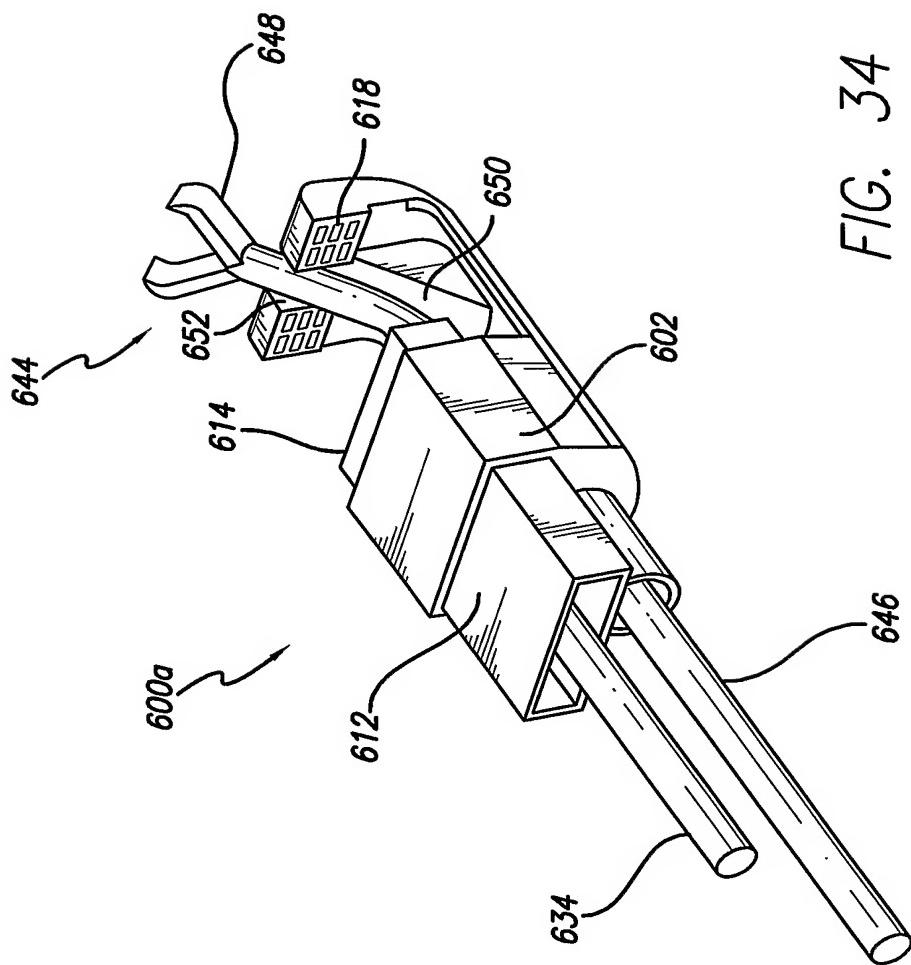


FIG. 34

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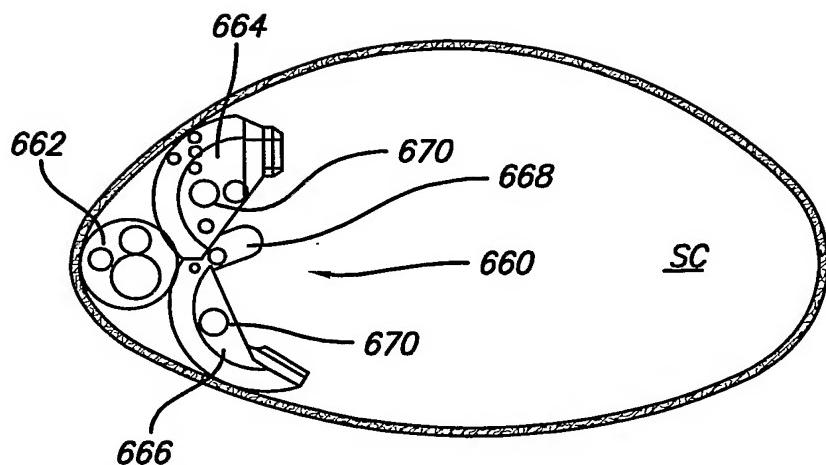


FIG. 35

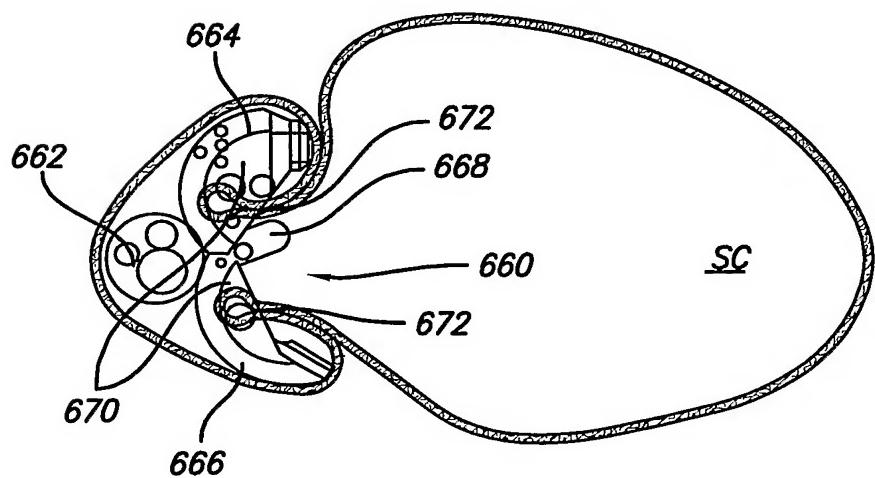


FIG. 36

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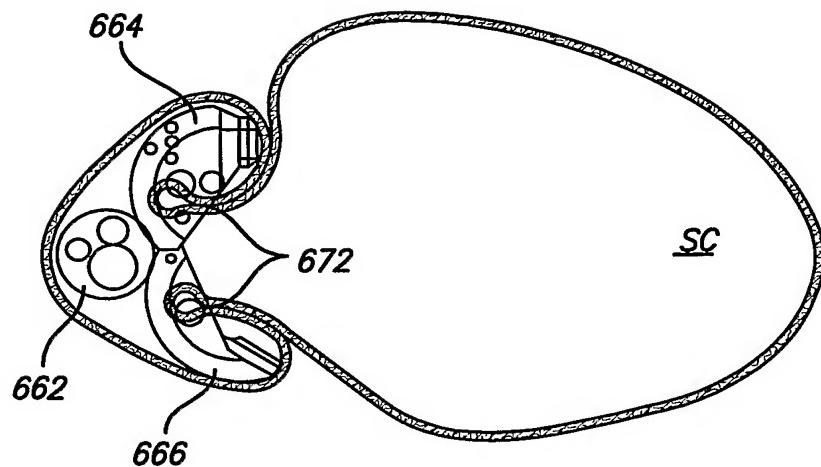


FIG. 37

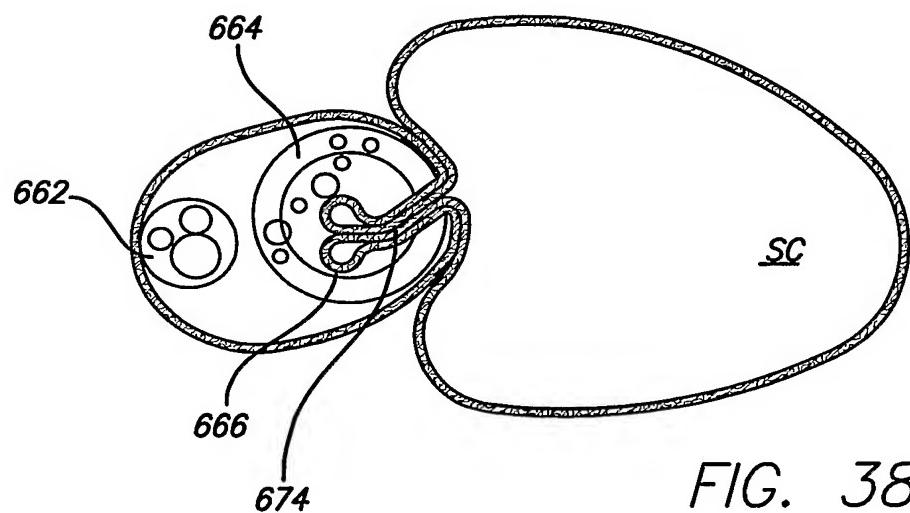


FIG. 38

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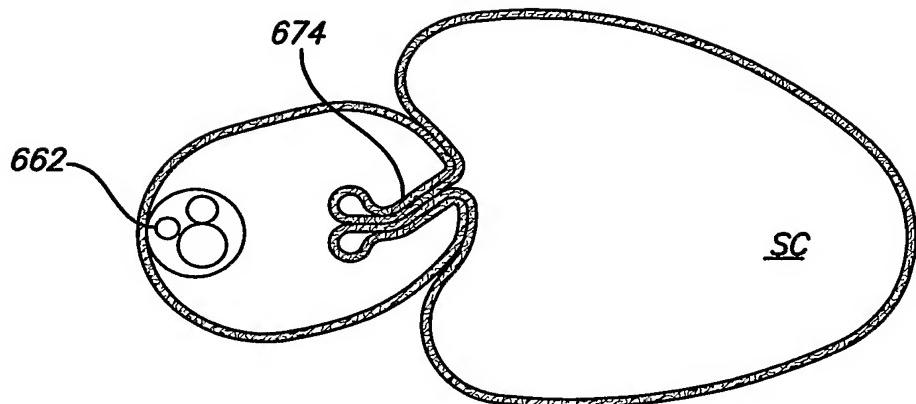


FIG. 39

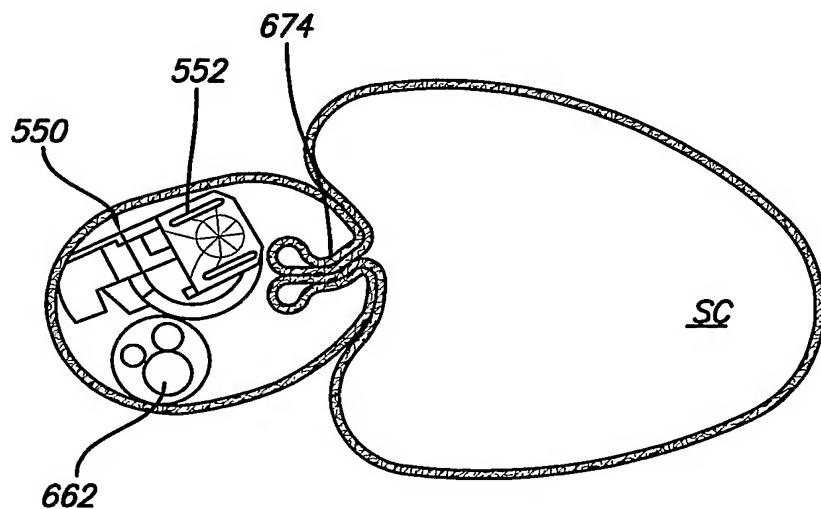


FIG. 40

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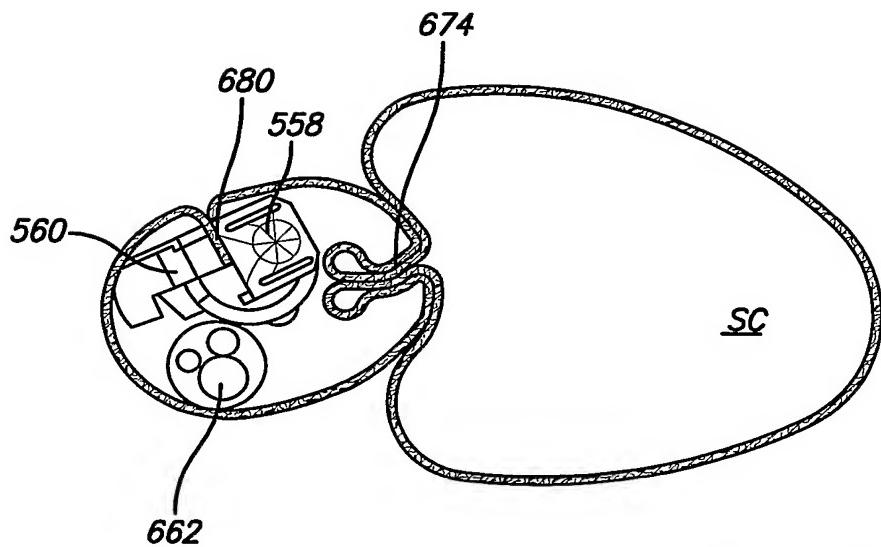


FIG. 41

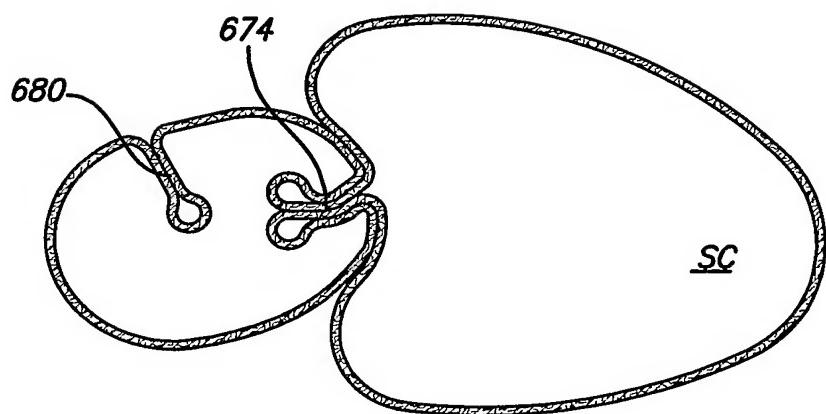


FIG. 42

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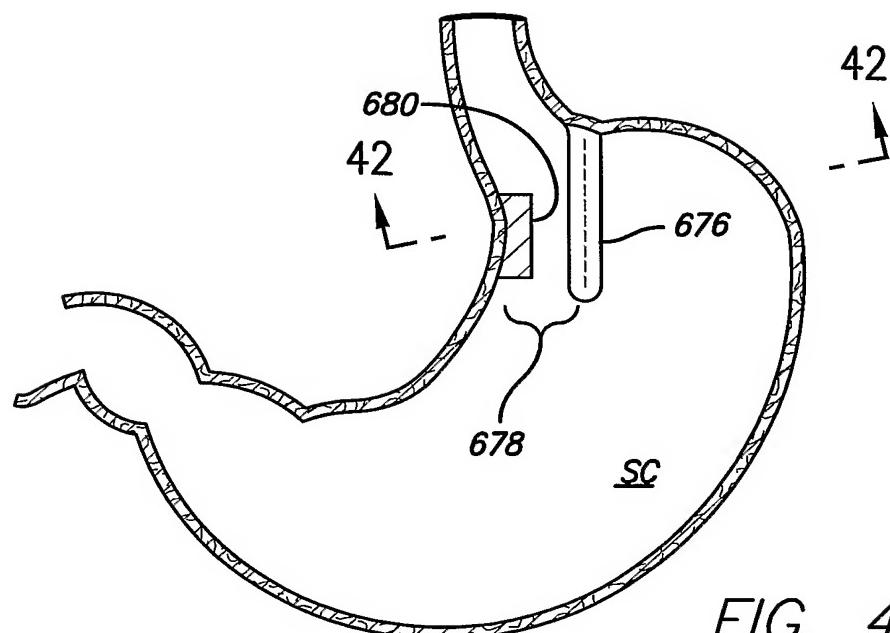


FIG. 43

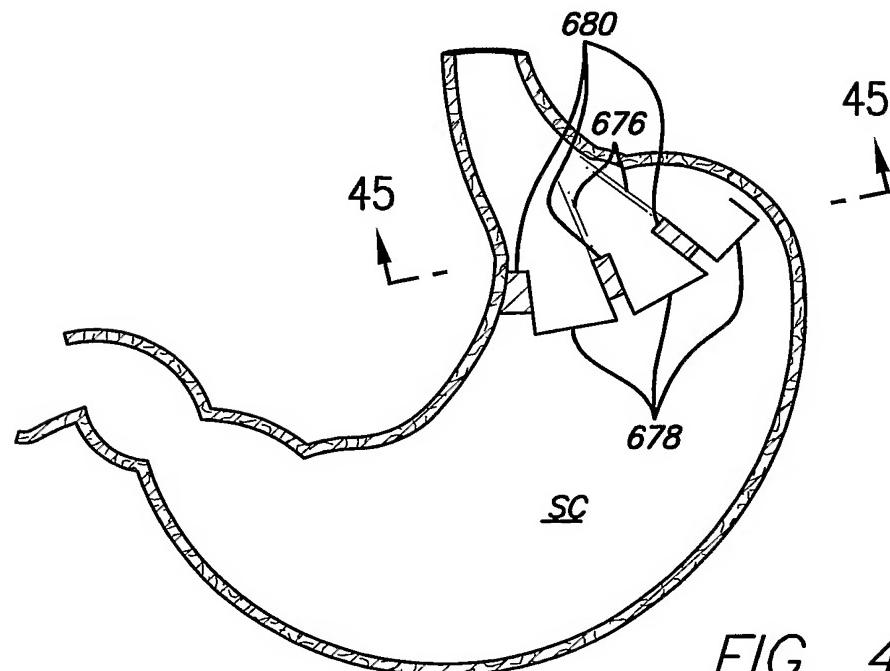


FIG. 44

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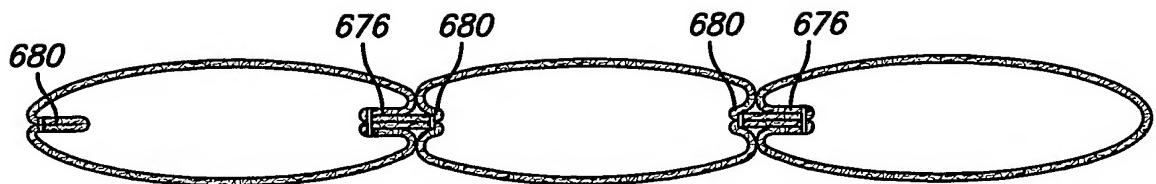


FIG. 45

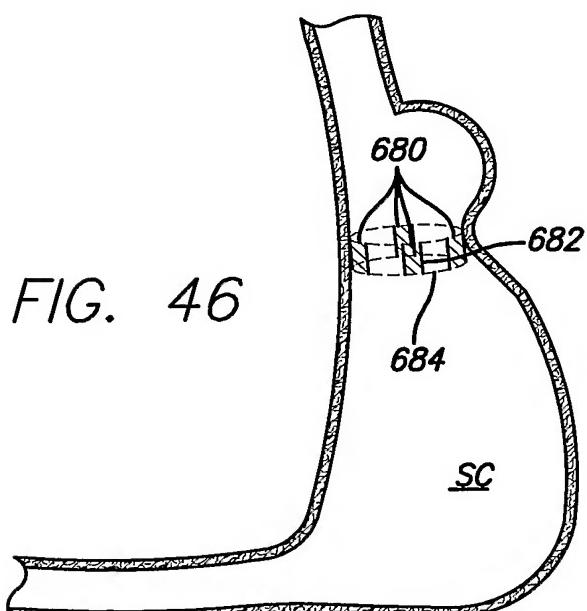


FIG. 46

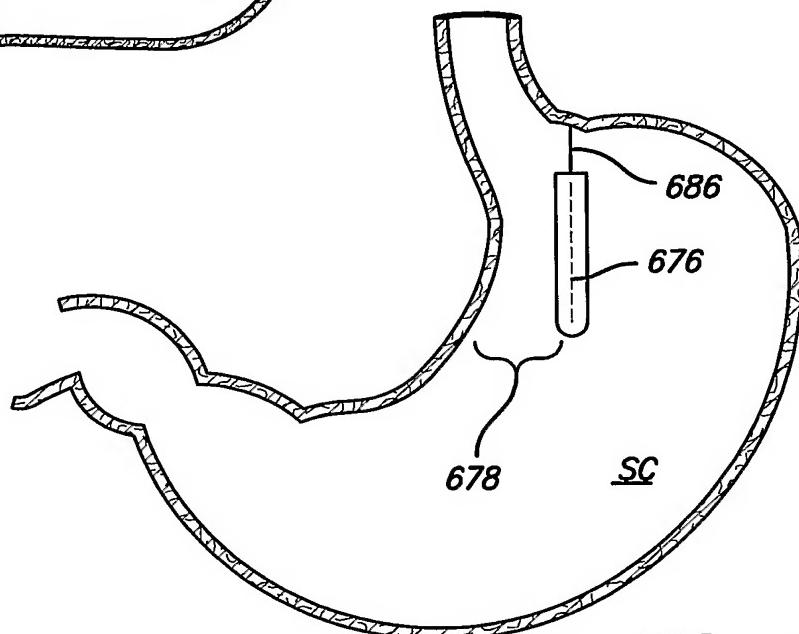


FIG. 47

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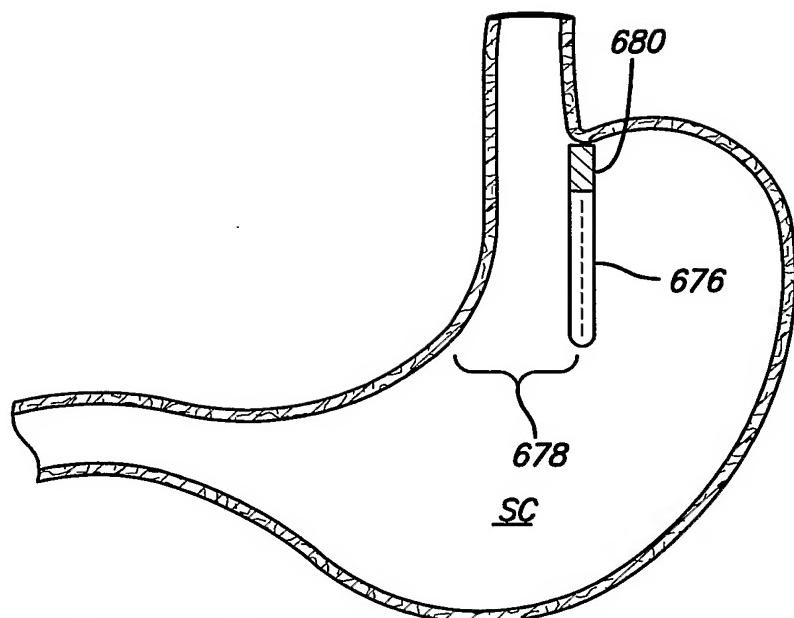


FIG. 48

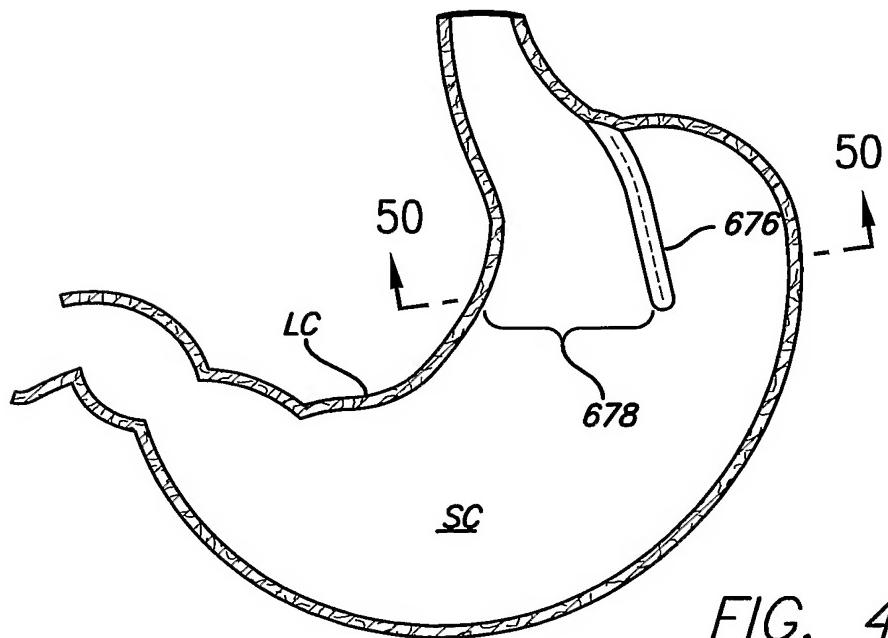


FIG. 49

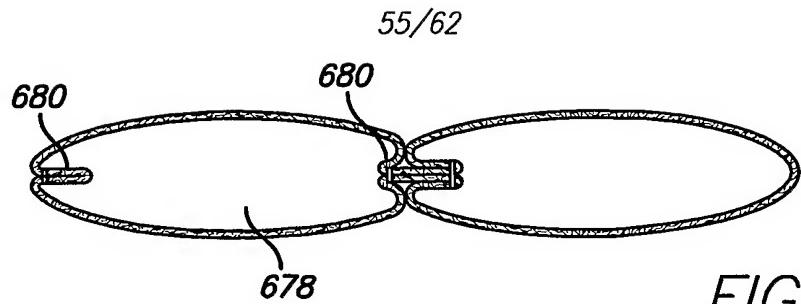


FIG. 50A

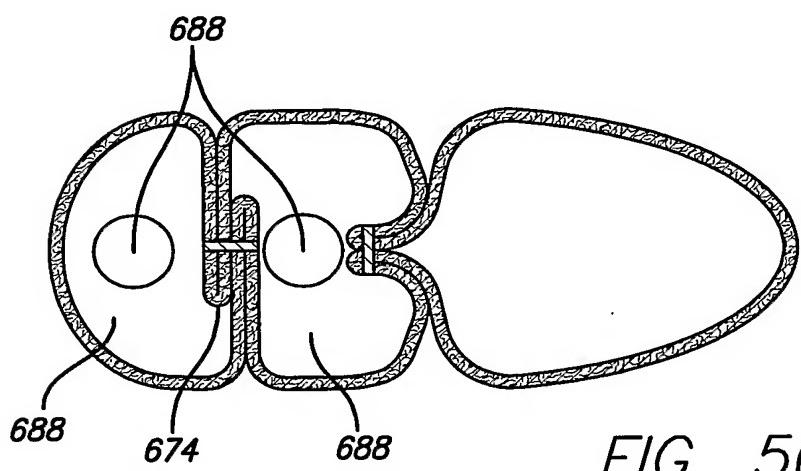


FIG. 50B

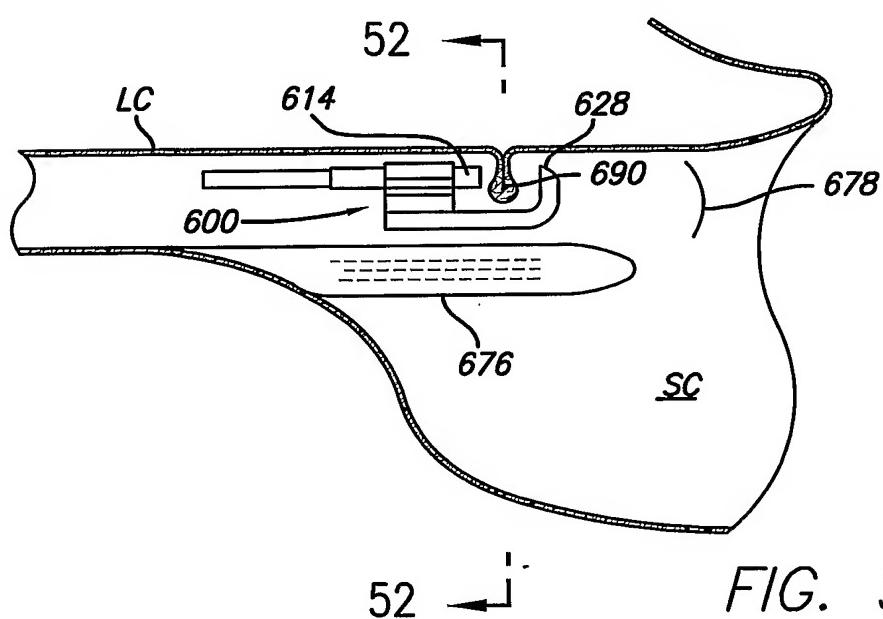


FIG. 51

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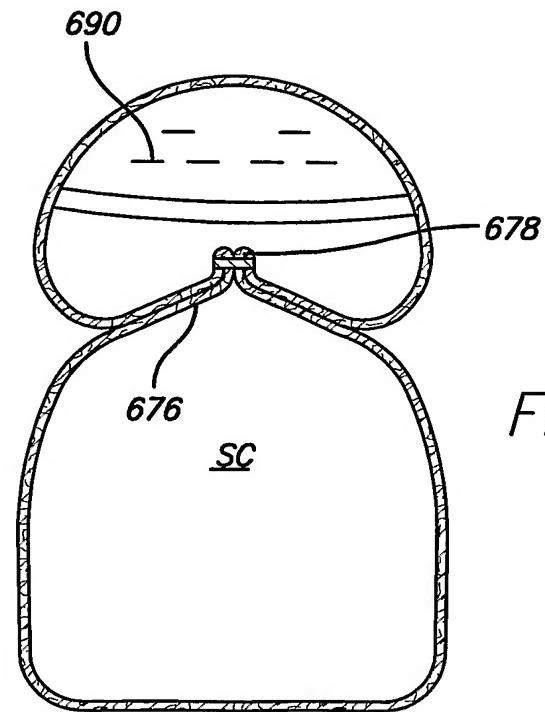


FIG. 52

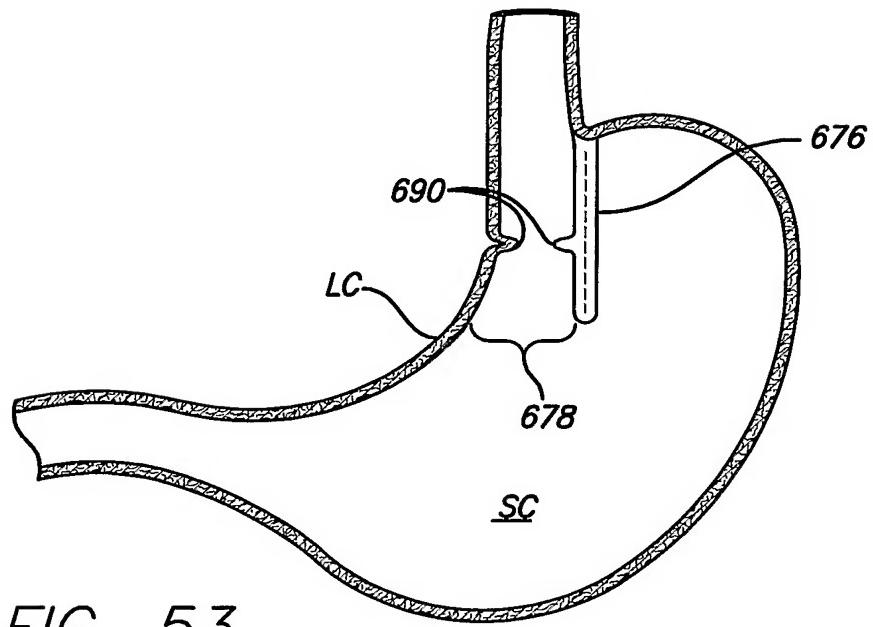


FIG. 53

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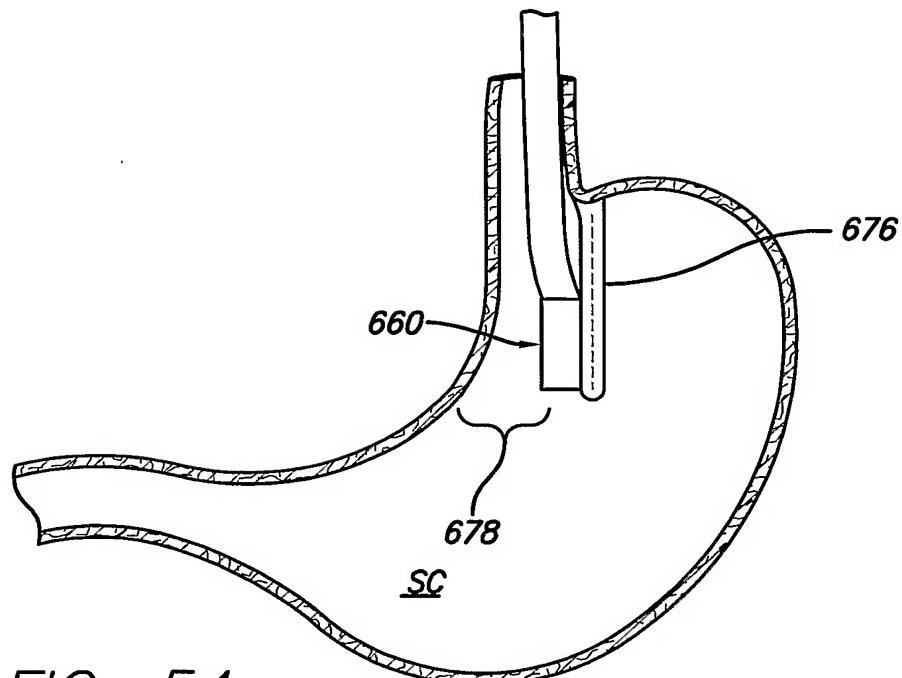


FIG. 54

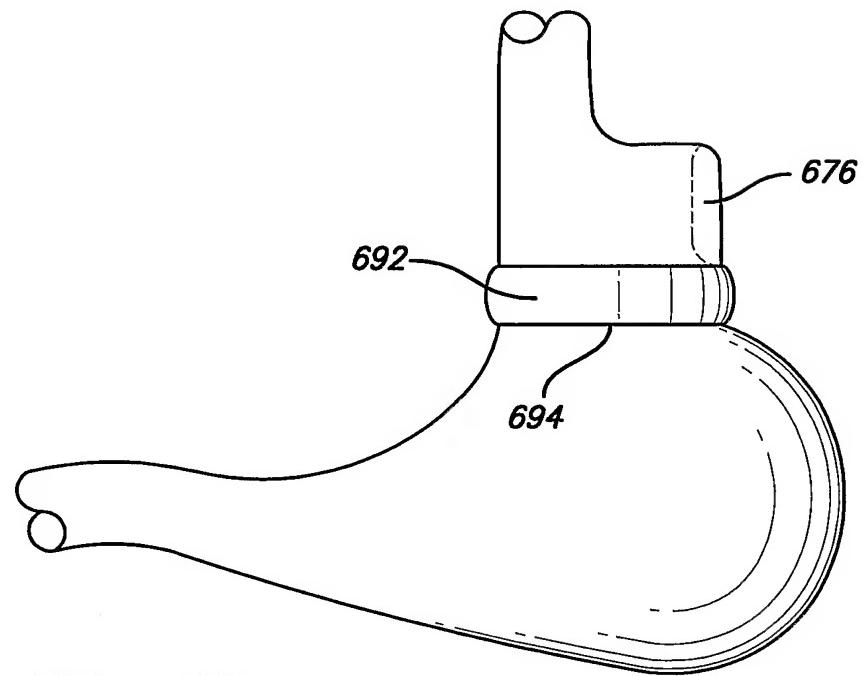


FIG. 55

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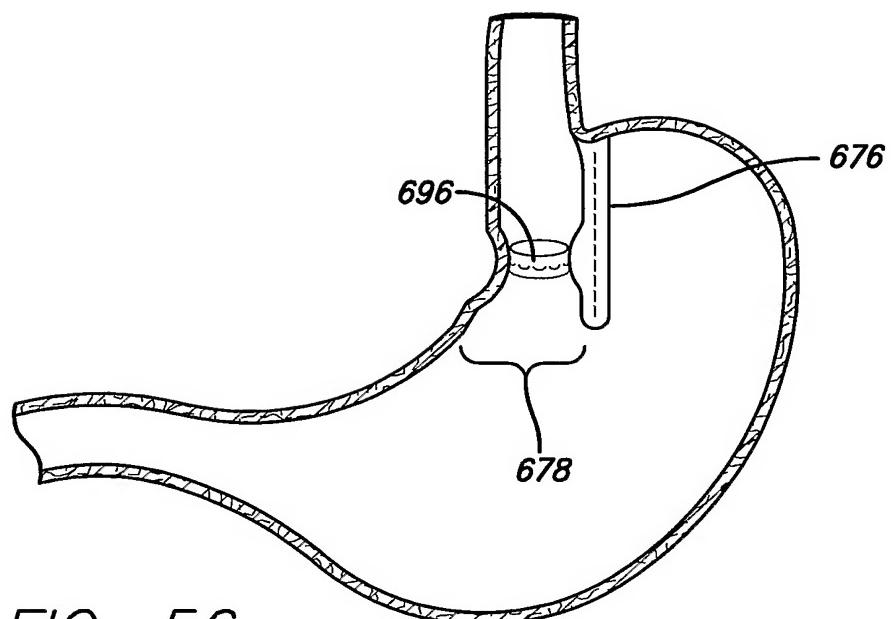


FIG. 56

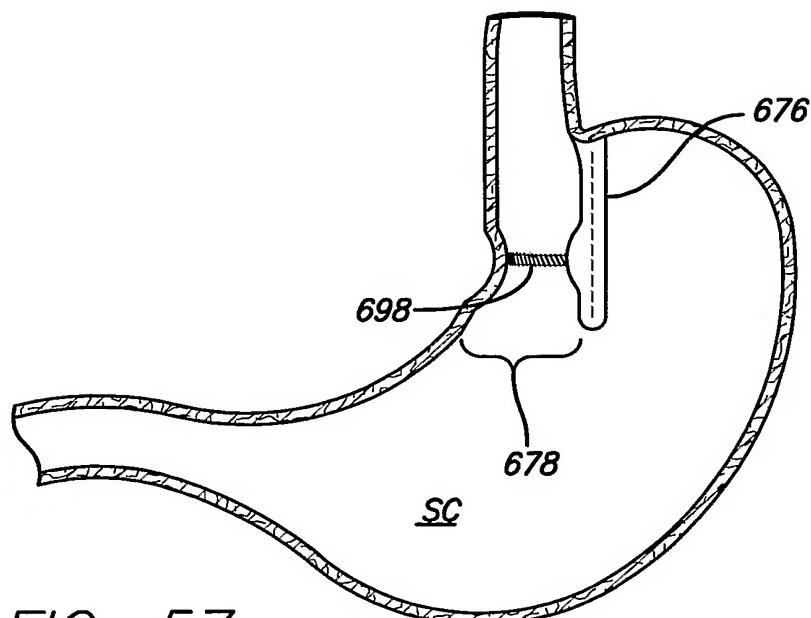


FIG. 57

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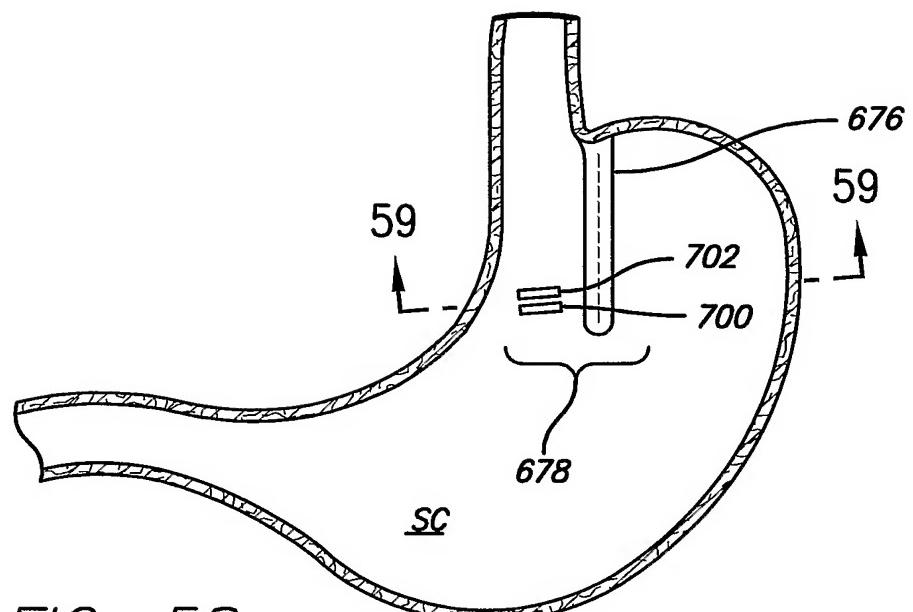


FIG. 58

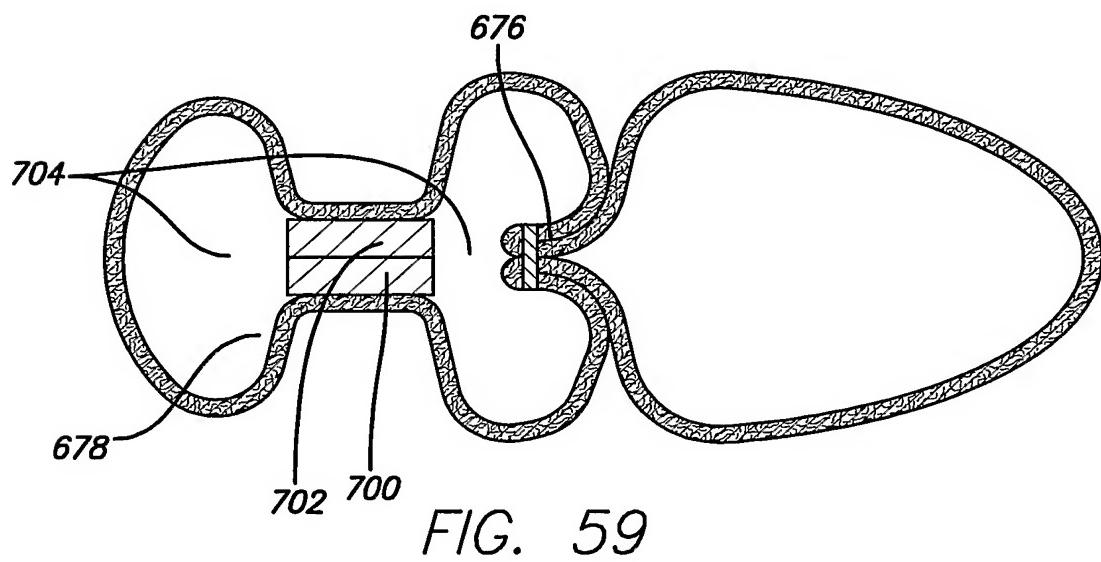


FIG. 59

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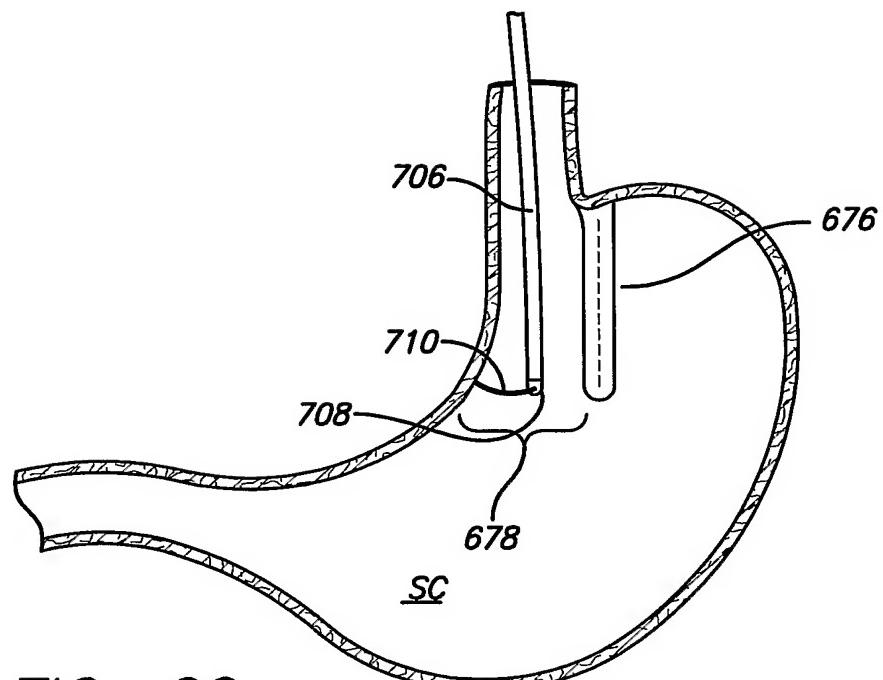


FIG. 60

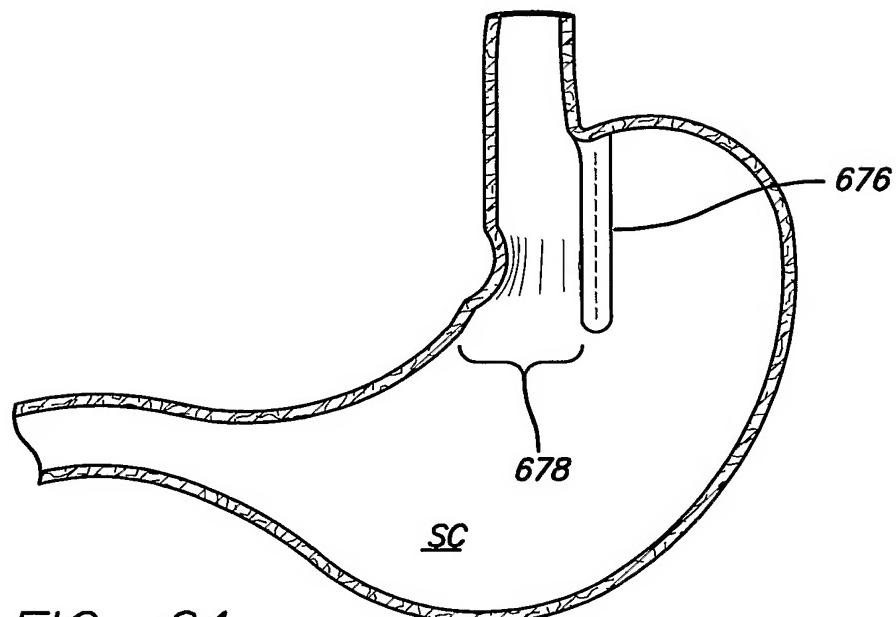


FIG. 61

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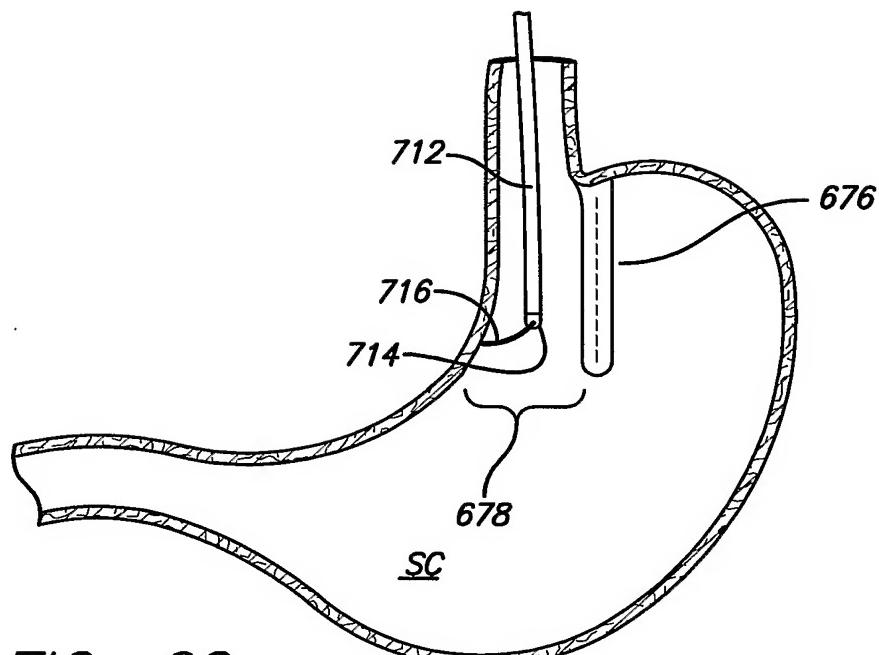


FIG. 62

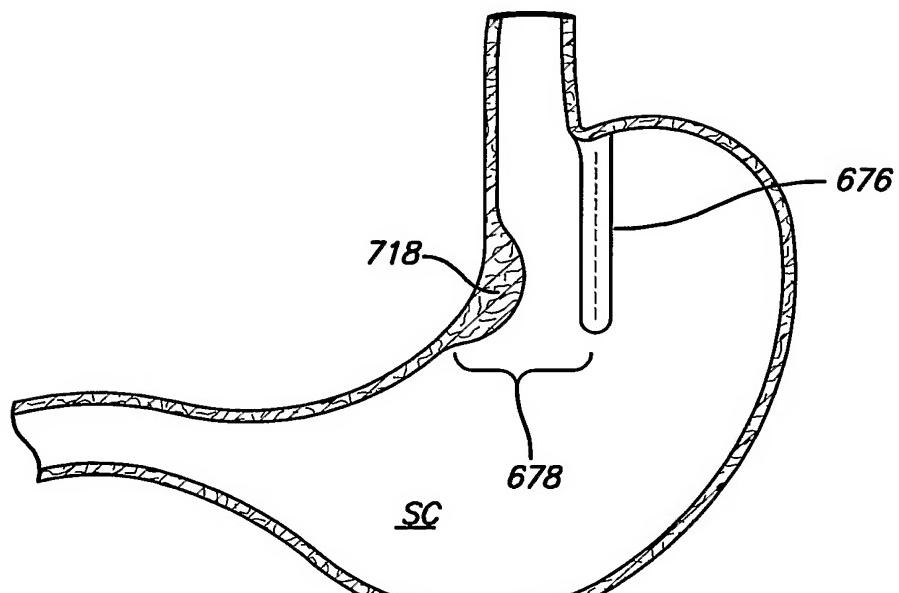


FIG. 63

62/62

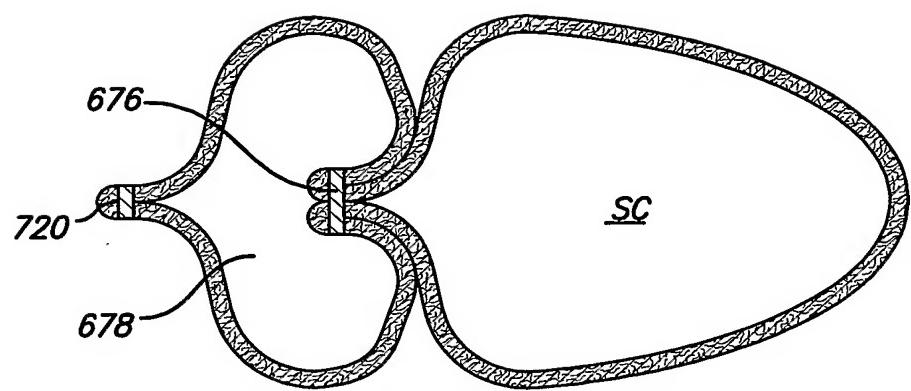


FIG. 64

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US2005/013740

A. CLASSIFICATION OF SUBJECT MATTER

A61B17/072 A61B17/068

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EP0-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2004/193190 A1 (LIDDICOAT JOHN R ET AL) 30 September 2004 (2004-09-30) paragraph '0097! - paragraph '0100!; figures 13-22	1-4, 7-9, 11-13, 17
Y	-----	5, 6, 16
X	US 5 403 326 A (HARRISON ET AL) 4 April 1995 (1995-04-04) cited in the application column 7, line 24 - line 59; figure 8a	1, 8-11, 14, 15
X	US 2004/092974 A1 (GANNOE JAMY ET AL) 13 May 2004 (2004-05-13) paragraph '0056! - paragraph '0058!; figures 7a, 7c paragraph '0060! paragraph '0063!; figure 9	1-5, 7-11
	-----	-/-

Further documents are listed in the continuation of box C.

Patent family members are listed in annex.

° Special categories of cited documents :

- "A" document defining the general state of the art which is not considered to be of particular relevance
- "E" earlier document but published on or after the international filing date
- "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- "O" document referring to an oral disclosure, use, exhibition or other means
- "P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search

Date of mailing of the international search report

22 November 2005

05/12/2005

Name and mailing address of the ISA

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Fax: (+31-70) 340-3016

Authorized officer

Ducreau, F

INTERNATIONAL SEARCH REPORT

International Application No PCT/US2005/013740

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2002/183768 A1 (DEEM MARK E ET AL) 5 December 2002 (2002-12-05) cited in the application column 11, line 3 - line 57; figures 9a,9b -----	1-4,11
Y	US 6 149 660 A (LAUFER ET AL) 21 November 2000 (2000-11-21) column 10, line 53 - line 55; figure 4 -----	5,6
Y	US 2002/120254 A1 (JULIAN CHRISTOPHER A ET AL) 29 August 2002 (2002-08-29) figure 5 -----	16
A	EP 0 625 335 A (UNITED STATES SURGICAL CORPORATION) 23 November 1994 (1994-11-23) figure 1 -----	11-13

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2005/013740

Box II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. Claims Nos.: **18-22**
because they relate to subject matter not required to be searched by this Authority, namely:
Rule 39.1(iv) PCT – Method for treatment of the human or animal body by surgery
2. Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- The additional search fees were accompanied by the applicant's protest.
 No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

International Application No PCT/US2005/013740

Patent document cited in search report		Publication date	Patent family member(s)			Publication date
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			DE 69406845 T2			09-04-1998
			ES 2109539 T3			16-01-1998